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the State of California; THE PEOPLE OF THE STATE OF CALIFORNIA, acting  
by and through the COUNTY OF MENDOCINO

**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF CALIFORNIA**

COUNTY OF MENDOCINO,  
a political subdivision of the  
State of California; THE PEOPLE  
OF THE STATE OF CALIFORNIA,  
acting by and through the COUNTY  
OF MENDOCINO,

Plaintiffs,

vs.

AMERISOURCEBERGEN DRUG  
CORPORATION; CARDINAL  
HEALTH, INC.; McKESSON  
CORPORATION; PURDUE PHARMA  
L.P.; PURDUE PHARMA, INC.; THE  
PURDUE FREDERICK COMPANY,  
INC.; TEVA PHARMACEUTICAL  
INDUSTRIES, LTD.; TEVA  
PHARMACEUTICALS USA, INC.;  
CEPHALON, INC.; JOHNSON &  
JOHNSON; JANSSEN  
PHARMACEUTICALS, INC.;  
ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC. n/k/a  
JANSSEN PHARMACEUTICALS,  
INC.; JANSSEN PHARMACEUTICA  
INC. n/k/a JANSSEN

Case No.: \_\_\_\_\_

**COMPLAINT FOR DAMAGES  
AND DEMAND FOR JURY  
TRIAL**

- (1) Public Nuisance;
- (2) Violations of Racketeer  
Influenced and Corrupt  
Organizations Act (RICO), 18  
U.S.C. § 1961 et seq.;
- (3) Violations of 18 U.S.C. § 1962  
et seq.;
- (4) Violations of the California  
False Advertising Act, Cal. Bus.  
& Prof. Code § 17500 et seq.;
- (5) Negligent Misrepresentation;
- (6) Fraud and Fraudulent  
Misrepresentation; and
- (7) Unjust Enrichment.

1 PHARMACEUTICALS, INC.; )  
2 NORAMCO, INC.; ENDO HEALTH )  
3 SOLUTIONS INC.; ENDO )  
4 PHARMACEUTICALS, INC.; )  
5 ALLERGAN PLC f/k/a ACTAVIS )  
6 PLS; WATSON )  
7 PHARMACEUTICALS, INC. n/k/a )  
8 ACTAVIS, INC.; WATSON )  
9 LABORATORIES, INC.; ACTAVIS )  
10 LLC; ACTAVIS PHARMA, INC. f/k/a )  
11 WATSON PHARMA, INC.; )  
12 MALLINCKRODT PLC; )  
13 MALLINCKRODT LLC;; and INSYS )  
14 THERAPEUTICS, INC. )

15 Defendants. )  
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Plaintiffs, COUNTY OF MENDOCINO, and THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Mendocino County Counsel, (collectively “Plaintiffs”) bring this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; Insys Therapeutics, Inc., McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively “Defendants”) and allege as follows:

## I. INTRODUCTION

1. Plaintiffs bring this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent and will be spent because of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.<sup>1</sup> Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.<sup>2</sup>

<sup>1</sup> As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

<sup>2</sup> See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

5. Plaintiffs also bring this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

## A. PLAINTIFFS.

7. The County is responsible for the public health, safety and welfare of its citizens.

8. The County has declared, *inter alia*, that opioid abuse, addiction, morbidity and mortality have created a serious public health and safety crisis, and

<sup>3</sup> See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).



1 is a public nuisance, and that the diversion of legally produced controlled  
2 substances into the illicit market causes or contributes to this public nuisance.

3 9. The distribution and diversion of opioids into California (“the  
4 State”), and into Mendocino County and surrounding areas (collectively,  
5 “Plaintiffs’ Community”), created the foreseeable opioid crisis and opioid public  
6 nuisance for which Plaintiffs here seek relief.

7 10. Plaintiffs directly and foreseeably sustained all economic damages  
8 alleged herein. Defendants’ conduct has exacted a financial burden for which the  
9 Plaintiffs seek relief. Categories of past and continuing sustained damages  
10 include, *inter alia*,: (1) costs for providing medical care, additional therapeutic,  
11 and prescription drug purchases, and other treatments for patients suffering from  
12 opioid-related addiction or disease, including overdoses and deaths; (2) costs for  
13 providing treatment, counseling, and rehabilitation services; (3) costs for  
14 providing treatment of infants born with opioid-related medical conditions; (4)  
15 costs associated with law enforcement and public safety relating to the opioid  
16 epidemic; (5) costs associated with providing care for children whose parents  
17 suffer from opioid-related disability or incapacitation and (6) costs associated with  
18 The County having to repair and remake its infrastructure, property and systems  
19 that have been damaged by Defendants’ actions, including, *inter alia*, its property  
20 and systems to treat addiction and abuse, to respond to and manage an elevated  
21 level of crime, to treat injuries, and to investigate and process deaths in Plaintiffs’  
22 Community. These damages have been suffered, and continue to be suffered,  
23 directly by the Plaintiffs.

24 11. Plaintiffs also seek the means to abate the epidemic created by  
25 Defendants’ wrongful and/or unlawful conduct.

26 12. The People have standing to bring an action for the opioid epidemic  
27 nuisance created by Defendants. Cal. Civ. Proc. Code § 731 (“A civil action may  
28 be brought in the name of the people of the State of California to abate a public

1 nuisance, as defined in Section 3480 of the Civil Code, by the . . . county counsel  
2 of any county in which the nuisance exists.”).

3 13. The County has standing to bring an action for damages incurred to  
4 its property by the public nuisance created by Defendants. Cal. Civ. Proc. Code §  
5 731 (“An action may be brought by any person whose property is injuriously  
6 affected, . . . and by the judgment in that action the nuisance may be enjoined or  
7 abated as well as damages recovered therefor.”).

8 14. The People have standing to bring this claim for injunctive relief and  
9 civil penalties under the California False Advertising Act. Cal. Bus. & Prof. Code  
10 §§ 17535, 17536.

11 15. The County has standing to recover damages incurred as a result of  
12 Defendants’ actions and omissions. Cal. Gov’t Code § 23004(a). The County has  
13 standing to bring claims under the federal RICO statute, pursuant to 18 U.S.C. §  
14 1961(3) (“persons” include entities which can hold legal title to property) and 18  
15 U.S.C. § 1964 (“persons” have standing).

16 **B. DEFENDANTS.**

17 **1. Manufacturer Defendants.**

18 16. The Manufacturer Defendants are defined below. At all relevant  
19 times, the Manufacturer Defendants have packaged, distributed, supplied, sold,  
20 placed into the stream of commerce, labeled, described, marketed, advertised,  
21 promoted and purported to warn or purported to inform prescribers and users  
22 regarding the benefits and risks associated with the use of the prescription opioid  
23 drugs. The Manufacturer Defendants, at all times, have manufactured and sold  
24 prescription opioids without fulfilling their legal duty to prevent diversion and  
25 report suspicious orders.

26 17. PURDUE PHARMA L.P. is a limited partnership organized under  
27 the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with  
28 its principal place of business in Stamford, Connecticut, and THE PURDUE

1 FREDERICK COMPANY, INC. is a Delaware corporation with its principal  
2 place of business in Stamford, Connecticut (collectively, “Purdue”).

3 18. Purdue manufactures, promotes, sells, and distributes opioids such as  
4 OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and  
5 Targiniq ER in the United States. OxyContin is Purdue’s best-selling opioid.  
6 Since 2009, Purdue’s annual nationwide sales of OxyContin have fluctuated  
7 between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800  
8 million. OxyContin constitutes roughly 30% of the entire market for analgesic  
9 drugs (painkillers).

10 19. CEPHALON, INC. is a Delaware corporation with its principal place  
11 of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL  
12 INDUSTRIES, LTD. (“Teva Ltd.”) is an Israeli corporation with its principal  
13 place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon,  
14 Inc. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a Delaware  
15 corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva  
16 USA acquired Cephalon in October 2011.

17 20. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids  
18 such as Actiq and Fentora in the United States. Actiq has been approved by the  
19 FDA only for the “management of breakthrough cancer pain in patients 16 years  
20 and older with malignancies who are already receiving and who are tolerant to  
21 around-the-clock opioid therapy for the underlying persistent cancer pain.”<sup>4</sup>  
22 Fentora has been approved by the FDA only for the “management of breakthrough  
23 pain in cancer patients 18 years of age and older who are already receiving and  
24 who are tolerant to around-the-clock opioid therapy for their underlying persistent  
25  
26

27 <sup>4</sup> *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral*  
28 *transmucosal lozenge, CII* (2009),  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020747s030lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf).

1 cancer pain.”<sup>5</sup> In 2008, Cephalon pled guilty to a criminal violation of the Federal  
 2 Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other  
 3 drugs, and agreed to pay \$425 million.<sup>6</sup>

4 21. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to  
 5 market and sell Cephalon products in the United States. Teva Ltd. conducts all  
 6 sales and marketing activities for Cephalon in the United States through Teva  
 7 USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd.  
 8 and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva  
 9 USA sells all former Cephalon branded products through its “specialty medicines”  
 10 division. The FDA-approved prescribing information and medication guide, which  
 11 is distributed with Cephalon opioids, discloses that the guide was submitted by  
 12 Teva USA, and directs physicians to contact Teva USA to report adverse events.

13 22. All of Cephalon’s promotional websites, including those for Actiq  
 14 and Fentora, display Teva Ltd.’s logo.<sup>7</sup> Teva Ltd.’s financial reports list  
 15 Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 –  
 16 the year immediately following the Cephalon acquisition – attributed a 22%  
 17 increase in its specialty medicine sales to “the inclusion of a full year of  
 18 Cephalon’s specialty sales,” including *inter alia* sales of Fentora®.<sup>8</sup> Through  
 19 interrelated operations like these, Teva Ltd. operates in the United States through  
 20 its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva  
 21

22 <sup>5</sup> *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal*  
 23 *tablet, CII* (2011),  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/021947s0151bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s0151bl.pdf).

24 <sup>6</sup> Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to  
 25 Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing  
 (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

26 <sup>7</sup> *E.g.*, ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited  
 27 Jan. 16, 2018).

28 <sup>8</sup> Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013),  
[http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ\\_TEVA\\_2012.pdf](http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf).

1 Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it  
2 not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct  
3 those companies' business in the United States itself. Upon information and  
4 belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and  
5 their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva  
6 Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon,  
7 Inc. are referred to as "Cephalon."

8 23. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania  
9 corporation with its principal place of business in Titusville, New Jersey, and is a  
10 wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey  
11 corporation with its principal place of business in New Brunswick, New Jersey.  
12 NORAMCO, INC. ("Noramco") is a Delaware company headquartered in  
13 Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016.  
14 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as  
15 JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its  
16 principal place of business in Titusville, New Jersey. JANSSEN  
17 PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS,  
18 INC., is a Pennsylvania corporation with its principal place of business in  
19 Titusville, New Jersey. J&J is the only company that owns more than 10% of  
20 Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding  
21 Janssen's products. Upon information and belief, J&J controls the sale and  
22 development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to  
23 J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen  
24 Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are  
25 referred to as "Janssen."

26 24. Janssen manufactures, promotes, sells, and distributes drugs in the  
27 United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic  
28 accounted for at least \$1 billion in annual sales. Until January 2015, Janssen

1 developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER.  
2 Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

3 25. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with  
4 its principal place of business in Malvern, Pennsylvania. ENDO  
5 PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health  
6 Solutions Inc. and is a Delaware corporation with its principal place of business in  
7 Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals  
8 Inc. are referred to as “Endo.”

9 26. Endo develops, markets, and sells prescription drugs, including the  
10 opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States.  
11 Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in  
12 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it  
13 accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and  
14 sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and  
15 hydrocodone products in the United States, by itself and through its subsidiary,  
16 Qualitest Pharmaceuticals, Inc.

17 27. ALLERGAN PLC is a public limited company incorporated in  
18 Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC  
19 acquired ALLERGAN PLC in March 2015, and the combined company changed  
20 its name to ALLERGAN PLC in January 2013. Before that, WATSON  
21 PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and  
22 the combined company changed its name to Actavis, Inc. as of January 2013 and  
23 then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a  
24 Nevada corporation with its principal place of business in Corona, California, and  
25 is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a  
26 Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is  
27 a Delaware corporation with its principal place of business in New Jersey and was  
28 formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware



1 limited liability company with its principal place of business in Parsippany, New  
2 Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them  
3 to market and sell its drugs in the United States. Upon information and belief,  
4 ALLERGAN PLC exercises control over these marketing and sales efforts and  
5 profits from the sale of Allergan/Actavis products ultimately inure to its benefit.  
6 ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis  
7 Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson  
8 Laboratories, Inc. are referred to as “Actavis.”

9 28. Actavis manufactures, promotes, sells, and distributes opioids,  
10 including the branded drugs Kadian and Norco, a generic version of Kadian, and  
11 generic versions of Duragesic and Opana, in the United States. Actavis acquired  
12 the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and  
13 began marketing Kadian in 2009.

14 29. MALLINCKRODT, PLC is an Irish public limited company  
15 headquartered in Staines-upon-Thames, United Kingdom, with its U.S.  
16 headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability  
17 company organized and existing under the laws of the State of Delaware.  
18 Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC.  
19 Mallinckrodt, PLC and Mallinckrodt, LLC are referred to as “Mallinckrodt.”

20 30. Mallinckrodt manufactures, markets, and sells drugs in the United  
21 States including generic oxycodone, of which it is one of the largest  
22 manufacturers. In July 2017 Mallinckrodt agreed to pay \$35 million to settle  
23 allegations brought by the Department of Justice that it failed to detect and notify  
24 the DEA of suspicious orders of controlled substances.

25 31. INSYS THERAPEUTICS, INC. is a Delaware corporation with its  
26 principal place of business in Chandler, Arizona. Insys’s principal product and  
27 source of revenue is Subsys.  
28

1           32.   Insys made thousands of payments to physicians nationwide,  
2 including in the State, ostensibly for activities including participating on speakers'  
3 bureaus, providing consulting services, assisting in post-marketing safety  
4 surveillance and other services, but in fact to deceptively promote and maximize  
5 the use of opioids.

6           33.   Subsys is a transmucosal immediate-release formulation (TIRF) of  
7 fentanyl, contained in a single-dose spray device intended for oral, under the  
8 tongue administration. Subsys was approved by the FDA solely for the treatment  
9 of breakthrough cancer pain.

10          34.   In 2016, Insys made approximately \$330 million in net revenue from  
11 Subsys. Insys promotes, sells, and distributes Subsys throughout the United  
12 States, the County, and Plaintiffs' Community.

13          35.   Insys's founder and owner was recently arrested and charged, along  
14 with other Insys executives, with multiple felonies in connection with an alleged  
15 conspiracy to bribe practitioners to prescribe Subsys and defraud insurance  
16 companies. Other Insys executives and managers were previously indicted.

17               **2. Distributor Defendants.**

18          36.   The Distributor Defendants also are defined below. At all relevant  
19 times, the Distributor Defendants have distributed, supplied, sold, and placed into  
20 the stream of commerce the prescription opioids, without fulfilling the  
21 fundamental duty of wholesale drug distributors to detect and warn of diversion of  
22 dangerous drugs for non-medical purposes. The Distributor Defendants  
23 universally failed to comply with federal and/or state law. The Distributor  
24 Defendants are engaged in "wholesale distribution," as defined under state and  
25 federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is  
26 responsible for the volume of prescription opioids plaguing Plaintiffs'  
27 Community.



1           37.   McKESSON CORPORATION (“McKesson”) at all relevant times,  
2 operated as a licensed distributor in California, licensed by the California State  
3 Board of Pharmacy and holding both wholesaler and out of state wholesaler  
4 distributor licenses. McKesson is a Delaware corporation. McKesson has its  
5 principal place of business located in San Francisco, California. McKesson  
6 operates distribution centers in Chino, Fullerton, Sacramento and Visalia,  
7 California.

8           38.   CARDINAL HEALTH, INC. (“Cardinal”) at all relevant times,  
9 operated as a licensed distributor in California, licensed by the California State  
10 Board of Pharmacy and holding both wholesaler and out of state wholesaler  
11 distributor licenses. Cardinal’s principal office is located in Dublin, Ohio.  
12 Cardinal operates a distribution center in Sacramento, California.

13           39.   AMERISOURCEBERGEN           DRUG           CORPORATION  
14 (“AmerisourceBergen”) at all relevant times, operated as a licensed distributor in  
15 California, licensed by the California State Board of Pharmacy and holding both  
16 wholesaler and out of state wholesaler distributor licenses. AmerisourceBergen is  
17 a Delaware corporation and its principal place of business is located in  
18 Chesterbrook, Pennsylvania.

19           40.   Defendants include the above referenced entities as well as their  
20 predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the  
21 extent that they are engaged in the manufacture, promotion, distribution, sale  
22 and/or dispensing of opioids.

23                           **III.   JURISDICTION & VENUE**

24           41.   This Court has subject matter jurisdiction under 28 U.S.C. § 1331  
25 based upon the federal claims asserted under the Racketeer Influenced and  
26 Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* (“RICO”). This Court has  
27 supplemental jurisdiction over Plaintiffs’ state law claims pursuant to 28 U.S.C. §  
28

1 1367 because those claims are so related to Plaintiffs' federal claims that they  
2 form part of the same case or controversy.

3 42. This Court has personal jurisdiction over Defendants because they  
4 conduct business in the State, purposefully direct or directed their actions toward  
5 the State, some or all consented to be sued in the State by registering an agent for  
6 service of process, they consensually submitted to the jurisdiction of the State  
7 when obtaining a manufacturer or distributor license, and because they have the  
8 requisite minimum contacts with the State necessary to constitutionally permit the  
9 Court to exercise jurisdiction.

10 43. This Court also has personal jurisdiction over all of the defendants  
11 under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over  
12 the named Defendants where the "ends of justice" require national service and  
13 Plaintiffs demonstrate national contacts. Here, the interests of justice require that  
14 Plaintiffs be allowed to bring all members of the nationwide RICO enterprise  
15 before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17*  
16 *Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796, 803 (N.D. Ohio 1998)  
17 (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, \*2  
18 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788  
19 F.2d 535, 539 (9th Cir. 1986)).

20 44. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18  
21 U.S.C. §1965 because a substantial part of the events or omissions giving rise to  
22 the claim occurred in this District and each Defendant transacted affairs and  
23 conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. §  
24 1391(b); 18 U.S.C. §1965(a).

#### IV. FACTUAL BACKGROUND

##### A. THE OPIOID EPIDEMIC.

###### 1. The National Opioid Epidemic.

45. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.<sup>9</sup>

46. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.<sup>10</sup>

47. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

<sup>9</sup> See Richard C. Dart et al., Trends in Opioid Analgesic Abuse and Mortality in the United States, 372 N. Eng. J. Med. 241 (2015).

<sup>10</sup> Katherine M. Keyes et al., Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).

1 f. Almost 5,500 people start to misuse prescription painkillers every  
2 day.<sup>11</sup>

3 48. The number of annual opioid prescriptions written in the United  
4 States is now roughly equal to the number of adults in the population.<sup>12</sup>

5 49. Many Americans are now addicted to prescription opioids, and the  
6 number of deaths due to prescription opioid overdose is unacceptable. In 2016,  
7 drug overdoses killed roughly 64,000 people in the United States, an increase of  
8 more than 22 percent over the 52,404 drug deaths recorded the previous year.<sup>13</sup>

9 50. Moreover, the CDC has identified addiction to prescription pain  
10 medication as the strongest risk factor for heroin addiction. People who are  
11 addicted to prescription opioid painkillers are forty times more likely to be  
12 addicted to heroin.<sup>14</sup>

13 51. Heroin is pharmacologically similar to prescription opioids. The  
14 majority of current heroin users report having used prescription opioids non-  
15 medically before they initiated heroin use. Available data indicates that the  
16 nonmedical use of prescription opioids is a strong risk factor for heroin use.<sup>15</sup>

17 52. The CDC reports that drug overdose deaths involving heroin  
18 continued to climb sharply, with heroin overdoses more than tripling in 4 years.  
19 This increase mirrors large increases in heroin use across the country and has been

20  
21 <sup>11</sup> See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of  
22 Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels  
(Nov. 1, 2011),  
[https://www.cdc.gov/media/releases/2011/p1101\\_flu\\_pain\\_killer\\_overdose.html](https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html).

23 <sup>12</sup> See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*,  
374 N. Eng. J. Med. 1480 (2016).

24 <sup>13</sup> See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human  
25 Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016),  
[https://www.cdc.gov/nchs/data/health\\_policy/monthly-drug-overdose-death-estimates.pdf](https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf).

26 <sup>14</sup> See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human  
27 Servs., *Today's Heroin Epidemic*,  
<https://www.cdc.gov/vitalsigns/heroin/index.html> (last updated July 7, 2015).

28 <sup>15</sup> See Wilson M. Compton, Relationship Between Nonmedical Prescription-  
Opioid Use and Heroin, 374 N. Eng. J. Med. 154 (2016).

1 shown to be closely tied to opioid pain reliever misuse and dependence. ***Past***  
 2 ***misuse of prescription opioids is the strongest risk factor for heroin initiation***  
 3 ***and use***, specifically among persons who report past-year dependence or abuse.  
 4 The increased availability of heroin, combined with its relatively low price  
 5 (compared with diverted prescription opioids) and high purity appear to be major  
 6 drivers of the upward trend in heroin use and overdose.<sup>16</sup>

7 53. The societal costs of prescription drug abuse are “huge.”<sup>17</sup>

8 54. Across the nation, local governments are struggling with a  
 9 pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day,  
 10 more than 90 Americans lose their lives after overdosing on opioids.<sup>18</sup>

11 55. The National Institute on Drug Abuse identifies misuse and addiction  
 12 to opioids as “a serious national crisis that affects public health as well as social  
 13 and economic welfare.”<sup>19</sup> The economic burden of prescription opioid misuse  
 14 alone is \$78.5 billion a year, including the costs of healthcare, lost productivity,  
 15 addiction treatment, and criminal justice expenditures.<sup>20</sup>

16  
17  
18  
19  
20 <sup>16</sup> See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—*  
*United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

21 <sup>17</sup> See Amicus Curiae Brief of Healthcare Distribution Management Association in  
 22 Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States*  
 23 *Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at \*10  
 [hereinafter Brief of HDMA].

24 <sup>18</sup> Opioid Crisis, NIH, National Institute on Drug Abuse (available at  
 25 <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited Sept. 19,  
 26 2017) (“Opioid Crisis, NIH”) (citing at note 1 Rudd RA, Seth P, David F, Scholl L,  
*Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–*  
*2015, MMWR MORB MORTAL WKLY REP.* 2016;65,  
 doi:10.15585/mmwr.mm655051e1).

27 <sup>19</sup> Opioid Crisis, NIH.

28 <sup>20</sup> *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden*  
*of Prescription Opioid Overdose, Abuse, and Dependence in the United States,*  
*2013, MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

1           56. The U.S. opioid epidemic is continuing, and drug overdose deaths  
2 nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that  
3 occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.<sup>21</sup>

4           57. The rate of death from opioid overdose has quadrupled during the  
5 past 15 years in the United States. Nonfatal opioid overdoses that require medical  
6 care in a hospital or emergency department have increased by a factor of six in the  
7 past 15 years.<sup>22</sup>

8           58. Every day brings a new revelation regarding the depth of the opioid  
9 plague: just to name one example, the New York Times reported in September  
10 2017 that the epidemic, which now claims 60,000 lives a year, is now killing  
11 babies and toddlers because ubiquitous, deadly opioids are “everywhere” and  
12 mistaken as candy.<sup>23</sup>

13           59. In 2016, the President of the United States declared an opioid and  
14 heroin epidemic.<sup>24</sup>

15           60. The epidemic of prescription pain medication and heroin deaths is  
16 devastating families and communities across the country.<sup>25</sup> Meanwhile, the  
17 manufacturers and distributors of prescription opioids extract billions of dollars of  
18 revenue from the addicted American public while public entities experience  
19

20  
21 <sup>21</sup> See Rose A. Rudd et al., Increases in Drug and Opioid-Involved Overdose  
22 Deaths—United States, 2010–2015, 65 *Morbidity & Mortality Wkly. Rep.* 1445  
(2016).

23 <sup>22</sup> See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—*  
*Misconceptions and Mitigation Strategies*, 374 *N. Eng. J. Med.* 1253 (2016).

24 <sup>23</sup> Julie Turkewitz, ‘*The Pills are Everywhere*’: *How the Opioid Crisis Claims Its*  
25 *Youngest Victims*, *N.Y. Times*, Sept. 20, 2017 (“‘It’s a cancer,’ said [grandmother  
of dead one-year old], of the nation’s opioid problem, ‘with tendrils that are going  
everywhere.’”).

26 <sup>24</sup> See Proclamation No. 9499, 81 *Fed. Reg.* 65,173 (Sept. 16, 2016) (proclaiming  
27 “Prescription Opioid and Heroin Epidemic Awareness Week”).

28 <sup>25</sup> See Presidential Memorandum – Addressing Prescription Drug Abuse and  
Heroin Use, 2015 *Daily Comp. Pres. Doc.* 743 (Oct. 21, 2015),  
<https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf>.



1 hundreds of millions of dollars of injury – if not more – caused by the reasonably  
2 foreseeable consequences of the prescription opioid addiction epidemic.

3 61. The prescription opioid manufacturers and distributors, including the  
4 Defendants, have continued their wrongful, intentional, and unlawful conduct,  
5 despite their knowledge that such conduct is causing and/or contributing to the  
6 national, state, and local opioid epidemic.

## 7 **2. The California Opioid Epidemic.**

8 62. California has been especially ravaged by the national opioid crisis.

9 63. More people die each year from drug overdoses in California than in  
10 any other state.<sup>26</sup> The State's death rate has continued to climb, increasing by 30  
11 percent from 1999 to 2015, according to the Center for Disease Control (CDC).<sup>27</sup>

12 64. In 2016, 1,925 Californians died due to prescription opioids.<sup>28</sup> This  
13 number is on par with other recent years: in 2015, 1,966 deaths in California were  
14 due just to prescription opioids (not including heroin); in 2014 that number was  
15 even higher at 2,024 prescription opioid deaths; and in 2013, 1,934 Californians  
16 died from a prescription opioid overdose.<sup>29</sup>

17 65. Of the 1,925 opioid-related deaths in California in 2016, fentanyl was  
18 a factor in at least 234 of them.<sup>30</sup> This is an increase of 47 percent for 2016.<sup>31</sup>  
19 Heroin-related deaths have risen by 67 percent in California since 2006.<sup>32</sup>

20  
21 <sup>26</sup> Kristina Davis, "How California ranks in the nation's opioid epidemic," *The San*  
22 *Diego Union-Tribune* (Nov. 8, 2017) available at  
[http://www.sandiegouniontribune.com/news/health/sd-me-opioid-conference-](http://www.sandiegouniontribune.com/news/health/sd-me-opioid-conference-20171108-story.html)  
23 [20171108-story.html](http://www.sandiegouniontribune.com/news/health/sd-me-opioid-conference-20171108-story.html) (last visited March 2, 2018).

24 <sup>27</sup> Soumya Karlamangla, "California's opioid death rate is among the national's  
25 lowest. Experts aren't sure why," *The Los Angeles Times* (Oct. 27, 2017) available  
26 at [http://www.latimes.com/health/la-me-ln-california-opioids-20171026-](http://www.latimes.com/health/la-me-ln-california-opioids-20171026-htmlstory.html)  
27 [htmlstory.html](http://www.latimes.com/health/la-me-ln-california-opioids-20171026-htmlstory.html) (last visited March 2, 2018).

28 <sup>28</sup> Davis, *supra*.

<sup>29</sup> California Department of Public Health, *California Opioid Overdose*  
*Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last  
visited March 2, 2018).

<sup>30</sup> Davis, *supra*.

<sup>31</sup> Karlamangla, *supra*.

1           66. The high number of deaths is due in part to the extraordinary number  
2 of opioids prescribed in the State. Over 23.6 million prescriptions for opioids were  
3 written in California in just 2016.<sup>33</sup>

4           67. The California Department of Public Health tracks the number of  
5 reported hospitalizations and emergency department visits due to prescription  
6 opioids.<sup>34</sup> In 2015, the last year for which information is currently available,  
7 California had 3,935 emergency department visits and 4,095 hospitalizations  
8 related to prescription opioid overdoses (excluding heroin).<sup>35</sup> The numbers were  
9 even higher in 2014, when 4,106 people visited the emergency department and  
10 4,482 people were hospitalized due to prescription opioid abuse.<sup>36</sup> In 2013, there  
11 were 3,964 emergency department visits and 4,344 hospitalizations for  
12 prescription opioid overdoses.<sup>37</sup> When emergency visits and hospitalizations  
13 include heroin, the numbers are even higher.<sup>38</sup>

14           68. Neonatal Abstinence Syndrome (NAS), a collection of symptoms  
15 newborn babies experience withdrawing from opioid medications taken by the  
16 mother, has increased dramatically in California, with the rate of infants born with  
17 NAS more than tripling from 2008 to 2013.<sup>39</sup> While the number of affected  
18

19 <sup>32</sup> California Department of Public Health, *State of California Strategies to Address*  
20 *Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in California*  
21 at 3 (June 2016), available at  
22 <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Document%20Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited March 2, 2018).

23 <sup>33</sup> California Department of Public Health, *California Opioid Overdose*  
24 *Surveillance Dashboard*, *supra*.

25 <sup>34</sup> *Id.*

26 <sup>35</sup> *Id.*

27 <sup>36</sup> *Id.*

28 <sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> California Child Welfare Co-Investment Partnership, *A Matter of Substance, Challenges and Responses to Parental Substance Use in Child Welfare*, at 5 (Summer 2017), available at [http://www.chhs.ca.gov/Child%20Welfare/CCW\\_Co-Invest\\_Insights\\_DIGITAL\\_FINAL\\_053017.pdf](http://www.chhs.ca.gov/Child%20Welfare/CCW_Co-Invest_Insights_DIGITAL_FINAL_053017.pdf) (last visited March 2, 2018).



1 newborns rose from 1,862 in 2008 to 3,007 in 2014, that number jumped by  
 2 another 21 percent in 2015.<sup>40</sup> This is despite a steady decline in the overall  
 3 number of birth in California during that same time.<sup>41</sup>

4  
 5 69. Reports from California's Office of Statewide Health Planning,  
 6 which collects data from licensed health care facilities, have shown a 95 percent  
 7 increase between 2008 and 2015 of newborns affected by drugs transmitted via  
 8 placenta or breast milk.<sup>42</sup>

9 70. The opioid epidemic has also had an impact on crime in California.  
 10 Pharmacy robberies have gone up by 163 percent in California over the last two  
 11 years, according to the DEA. The DEA recorded 90 incidents in 2015, 154 in  
 12 2016 and, through mid-November of 2017, that number had climbed to 237.<sup>43</sup>  
 13 Most perpetrators were after prescription opioids.<sup>44</sup> In addition, fentanyl seizures  
 14 at California ports increased 266 percent in fiscal year 2017.<sup>45</sup>

### 15 **3. The Opioid Epidemic in Plaintiffs' Community.**

16 71. The opioid epidemic is particularly devastating in Plaintiffs'  
 17 Community.

18  
 19  
 20 <sup>40</sup> Cheryl Clark, "Report Shows Spike in San Diego County Babies Born with  
 21 Drugs in their Systems," *KPBS* (April 17, 2017), available at  
 22 <http://www.kpbs.org/news/2017/apr/17/report-shows-spike-san-diego-county-babies-born-dr/> (last visited March 2, 2018).

<sup>41</sup> *Id.*

23 <sup>42</sup> California Child Welfare Co-Investment Partnership, *supra*, at 3.

24 <sup>43</sup> Ed Fletcher, "What's behind the spike in drug store robberies?" *The Sacramento*  
 25 *Bee*, Dec. 8, 2017 (available at  
 26 <http://www.sacbee.com/news/local/crime/article188636384.html> (last visited  
 March 2, 2018)).

<sup>44</sup> *Id.*

27 <sup>45</sup> United State Department of Justice, The United States Attorney's Office,  
 28 Southern District of California, *U.S. Attorney Appoints Opioid Coordinators* (Feb.  
 8, 2018) available at <https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators> (last visited March 2, 2018).

72. In 2016, the County endured 17 deaths due to opioid overdoses, for a death rate of 17.3 per 100,000 people, the fifth highest in the State.<sup>46</sup> In 2015, the County's opioid overdose death rate was in the highest quartile in the State with a rate of 15 deaths per 100,000 residents.<sup>47</sup> In 2014 the death rate was 16.96.<sup>48</sup>

73. This is part of a long-standing trend. From 2009 to 2013, the County had 38 deaths due to opioid pharmaceuticals, for the ninth highest death rate in the State.<sup>49</sup>

74. From 2012 to 2014, the County suffered 52 deaths due to drug overdoses for a drug overdose mortality rate of 20 deaths per 100,000 residents.<sup>50</sup>

75. Prescription opioids have also been responsible for a high rate of emergency department visits in the County. In 2016, Mendocino County had a rate of 30.6 emergency department visits per 100,000 residents due to opioid overdoses (excluding heroin).<sup>51</sup>

<sup>46</sup> California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last visited April 20, 2018) (Mendocino County specific page).

<sup>47</sup> Public Health Institute, *Tackling An Epidemic: An Assessment of the California Opioid Safety Coalitions Network*, at p. 11, available at <https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27ttdpzxmbclj7cxq99alz.pdf> (last visited April 20, 2018); *see also* Safe Rx Mendocino, Opioid Safety Coalition, available at <https://www.saferxmendocino.com/> (last visited April 21, 2018).

<sup>48</sup> Safe Rx Mendocino, Opioid Safety Coalition, available at <https://www.saferxmendocino.com/> (last visited April 21, 2018).

<sup>49</sup> California Department of Public Health, *State of California Strategies to Address Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in California* at 4 (June 2016), available at <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Document%20Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited April 20, 2018).

<sup>50</sup> County Health Rankings & Roadmaps, *Drug overdose deaths*, available at <http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/data> (last visited April 20, 2018).

<sup>51</sup> California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last visited April 20, 2018) (Mendocino County specific page).

1           76. The CDC has tracked prescription rates per county in the United  
 2 States, identifying the geographic “hotspots” for rates of opioid prescriptions.<sup>52</sup>  
 3 The CDC has calculated the geographic distribution at county levels of opioid  
 4 prescriptions dispensed per 100 persons,<sup>53</sup> revealing that Mendocino County has  
 5 been a consistent hotspot over at least the past decade.

6           77. The CDC’s statistics prove that the opioid prescription rates in  
 7 Mendocino County have exceeded any legitimate medical, scientific, or industrial  
 8 purpose. The overall opioid prescribing rate in 2016 was 66.5 prescriptions per  
 9 100 people nationally and 44.8 in California.<sup>54</sup> However, in Mendocino County,  
 10 California, the 2016 prescription rate was 105.1 per 100 people – more than one  
 11 prescription for every man, woman and child in Mendocino County and one of the  
 12 highest prescribing rates in the State.<sup>55</sup> This is down from the 2015 prescribing  
 13 rate for Mendocino County which was 118.2 per 100 people.<sup>56</sup>

14           78. Unfortunately, the 2015 and 2016 high rates of opioid prescriptions  
 15 were not an aberration for Mendocino County. Consistently, the opioid  
 16 prescribing rates in Mendocino County have been among the highest in the state,  
 17 significantly greater than the national and state averages, and well more than one  
 18 prescription per person living in the County. Compared to a national average of  
 19  
 20

21 <sup>52</sup> U.S. Prescribing Rate Maps, CDC, available at  
 22 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 23 2017).

24 <sup>53</sup> *Id.*

25 <sup>54</sup> *Id.* See also U.S. State Prescribing Rates, 2016, available at  
 26 <https://www.cdc.gov/drugoverdose/maps/rxstate2016.html> (last visited April 18,  
 27 2018).

28 <sup>55</sup> U.S. County Prescribing Rates, 2016, (reporting for “Mendocino, CA” here and  
 below) CDC available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited April 18,  
 2018).

<sup>56</sup> U.S. County Prescribing Rates, 2015, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html> (last visited April 18,  
 2018).

1 75.6 opioid prescriptions per 100 people in 2014<sup>57</sup> and 52.7 in California,<sup>58</sup> the  
 2 Mendocino County opioid prescription rate was 127.2 per 100 people.<sup>59</sup> In 2013,  
 3 the national average was 78.1 opioid prescriptions per 100 people,<sup>60</sup> but the opioid  
 4 prescription rate in Mendocino County was 129.4 per 100 people.<sup>61</sup> Compared to  
 5 a national average of 81.3 opioid prescriptions per 100 people in 2012,<sup>62</sup> the  
 6 opioid prescription rate in Mendocino County was 137.2 per 100 people that year  
 7 – an all-time high for Mendocino County.<sup>63</sup> In 2011, the national average was  
 8 80.9 opioid prescriptions per 100 people,<sup>64</sup> but the opioid prescription rate in  
 9 Mendocino County was 137 per 100 people.<sup>65</sup> Compared to a national average of  
 10 81.2 opioid prescriptions per 100 people in 2010,<sup>66</sup> the Mendocino County opioid

11  
 12 <sup>57</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 13 2017).

14 <sup>58</sup> U.S. State Prescribing Rates, 2014, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxstate2014.html> (last visited Dec. 11,  
 15 2017).

16 <sup>59</sup> U.S. County Prescribing Rates, 2014, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html> (last visited April 18,  
 17 2018).

18 <sup>60</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 19 2017).

20 <sup>61</sup> U.S. County Prescribing Rates, 2013, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2013.html> (last visited April 18,  
 21 2018).

22 <sup>62</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 23 2017).

24 <sup>63</sup> U.S. County Prescribing Rates, 2012, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html> (last visited April 18,  
 25 2018).

26 <sup>64</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 27 2017).

28 <sup>65</sup> U.S. County Prescribing Rates, 2011, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html> (last visited April 18,  
 2018).

<sup>66</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 2017).

1 prescription rate was 135.1 per 100 people.<sup>67</sup> In 2009, the national average was  
 2 79.5 opioid prescriptions per 100 people,<sup>68</sup> but the rate in Mendocino County was  
 3 129.4.5 per 100.<sup>69</sup> Compared to a national average of 78.2 opioid prescriptions per  
 4 100 people in 2008<sup>70</sup> and 55.1 in California,<sup>71</sup> the Mendocino County rate was  
 5 128.6 per 100 people.<sup>72</sup> In 2007, the national average was 75.9 opioid  
 6 prescriptions per 100 people,<sup>73</sup> but the Mendocino County rate was 121.6 per 100  
 7 people.<sup>74</sup> Compared to a national average of 72.4 opioid prescriptions per 100  
 8 people prescribed opioids in 2006,<sup>75</sup> the Mendocino County rate was 114.1 per  
 9 100 people.<sup>76</sup>

10  
 11  
 12 <sup>67</sup> U.S. County Prescribing Rates, 2010, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html> (last visited April 18,  
 13 2018).

14 <sup>68</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 15 2017).

16 <sup>69</sup> U.S. County Prescribing Rates, 2009, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2009.html> (last visited April 18,  
 17 2018).

18 <sup>70</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 19 2017).

20 <sup>71</sup> U.S. State Prescribing Rates, 2008, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxstate2008.html> (last visited Dec. 11,  
 21 2017).

22 <sup>72</sup> U.S. County Prescribing Rates, 2008, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2008.html> (last visited April 18,  
 23 2018).

24 <sup>73</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,,  
 25 2017).

26 <sup>74</sup> U.S. County Prescribing Rates, 2007, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2007.html> (last visited April 18,  
 27 2018).

28 <sup>75</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 2017).

<sup>76</sup> U.S. County Prescribing Rates, 2006, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2006.html> (last visited April 18,  
 2018).

1           79. The sheer volume of these dangerously addictive drugs was destined  
2 to create the present crisis of addiction, abuse, and overdose deaths.

3           **B. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE,**  
4           **AND UNFAIR MARKETING OF OPIOIDS.**

5           80. The opioid epidemic did not happen by accident.

6           81. Before the 1990s, generally accepted standards of medical practice  
7 dictated that opioids should only be used short-term for acute pain, pain relating to  
8 recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the  
9 lack of evidence that opioids improved patients' ability to overcome pain and  
10 function, coupled with evidence of greater pain complaints as patients developed  
11 tolerance to opioids over time and the serious risk of addiction and other side  
12 effects, the use of opioids for chronic pain was discouraged or prohibited. As a  
13 result, doctors generally did not prescribe opioids for chronic pain.

14           82. Each Manufacturer Defendant has conducted, and has continued to  
15 conduct, a marketing scheme designed to persuade doctors and patients that  
16 opioids can and should be used for chronic pain, resulting in opioid treatment for a  
17 far broader group of patients who are much more likely to become addicted and  
18 suffer other adverse effects from the long-term use of opioids. In connection with  
19 this scheme, each Manufacturer Defendant spent, and continues to spend, millions  
20 of dollars on promotional activities and materials that falsely deny or trivialize the  
21 risks of opioids while overstating the benefits of using them for chronic pain.

22           83. The Manufacturer Defendants have made false and misleading  
23 claims, contrary to the language on their drugs' labels, regarding the risks of using  
24 their drugs that: (1) downplayed the serious risk of addiction; (2) created and  
25 promoted the concept of "pseudoaddiction" when signs of actual addiction began  
26 appearing and advocated that the signs of addiction should be treated with more  
27 opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction;  
28 (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied



1 the risks of higher opioid dosages; and (6) exaggerated the effectiveness of  
 2 “abuse-deterrent” opioid formulations to prevent abuse and addiction. The  
 3 Manufacturer Defendants have also falsely touted the benefits of long-term opioid  
 4 use, including the supposed ability of opioids to improve function and quality of  
 5 life, even though there was no scientifically reliable evidence to support the  
 6 Manufacturer Defendants’ claims.

7 84. The Manufacturer Defendants have disseminated these common  
 8 messages to reverse the popular and medical understanding of opioids and risks of  
 9 opioid use. They disseminated these messages directly, through their sales  
 10 representatives, in speaker groups led by physicians the Manufacturer Defendants  
 11 recruited for their support of their marketing messages, and through unbranded  
 12 marketing and industry-funded front groups.

13 85. The Manufacturer Defendants’ efforts have been wildly successful.  
 14 Opioids are now the most prescribed class of drugs. Globally, opioid sales  
 15 generated \$11 billion in revenue for drug companies in 2010 alone; sales in the  
 16 United States have exceeded \$8 billion in revenue annually since 2009.<sup>77</sup> In an  
 17 open letter to the nation’s physicians in August 2016, the then-U.S. Surgeon  
 18 General expressly connected this “urgent health crisis” to “heavy marketing of  
 19 opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that  
 20 opioids are not addictive when prescribed for legitimate pain.”<sup>78</sup> This epidemic  
 21 has resulted in a flood of prescription opioids available for illicit use or sale (the  
 22 supply), and a population of patients physically and psychologically dependent on  
 23 them (the demand). And when those patients can no longer afford or obtain  
 24

25 <sup>77</sup> See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune,  
 26 Nov. 9, 2011, [http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/)  
 27 [medicine/](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/); David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times,  
 28 Aug. 10, 2016, [https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95)  
[a121aa8abd95](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95).

<sup>78</sup> Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016),  
<http://turnthetidex.org/>.

1 opioids from licensed dispensaries, they often turn to the street to buy prescription  
2 opioids or even non-prescription opioids, like heroin.

3 86. The Manufacturer Defendants intentionally continued their conduct,  
4 as alleged herein, with knowledge that such conduct was creating the opioid  
5 nuisance and causing the harms and damages alleged herein.

6 **1. Each Manufacturer Defendant Used Multiple Avenues to**  
7 **Disseminate Their False and Deceptive Statements about Opioids.**

8 87. The Manufacturer Defendants spread their false and deceptive  
9 statements by marketing their branded opioids directly to doctors and patients in  
10 and around the State, including in Plaintiffs' Community. Defendants also  
11 deployed seemingly unbiased and independent third parties that they controlled to  
12 spread their false and deceptive statements about the risks and benefits of opioids  
13 for the treatment of chronic pain throughout the State and Plaintiffs' Community.

14 88. The Manufacturer Defendants employed the same marketing plans  
15 and strategies and deployed the same messages in and around the State, including  
16 in Plaintiffs' Community, as they did nationwide. Across the pharmaceutical  
17 industry, "core message" development is funded and overseen on a national basis  
18 by corporate headquarters. This comprehensive approach ensures that the  
19 Manufacturer Defendants' messages are accurately and consistently delivered  
20 across marketing channels – including detailing visits, speaker events, and  
21 advertising – and in each sales territory. The Manufacturer Defendants consider  
22 this high level of coordination and uniformity crucial to successfully marketing  
23 their drugs.

24 89. The Manufacturer Defendants ensure marketing consistency  
25 nationwide through national and regional sales representative training; national  
26 training of local medical liaisons, the company employees who respond to  
27 physician inquiries; centralized speaker training; single sets of visual aids, speaker  
28 slide decks and sales training materials; and nationally coordinated advertising.



1 The Manufacturer Defendants' sales representatives and physician speakers were  
2 required to stick to prescribed talking points, sales messages, and slide decks, and  
3 supervisors rode along with them periodically to both check on their performance  
4 and compliance.

5 **a) Direct Marketing.**

6 90. The Manufacturer Defendants' direct marketing of opioids generally  
7 proceeded on two tracks. First, each Manufacturer Defendant conducted and  
8 continues to conduct advertising campaigns touting the purported benefits of their  
9 branded drugs. For example, upon information and belief, the Manufacturer  
10 Defendants spent more than \$14 million on medical journal advertising of opioids  
11 in 2011, nearly triple what they spent in 2001.

12 91. Many of the Manufacturer Defendants' branded ads deceptively  
13 portrayed the benefits of opioids for chronic pain. For example, Endo distributed  
14 and made available on its website [opana.com](http://opana.com) a pamphlet promoting Opana ER  
15 with photographs depicting patients with physically demanding jobs like  
16 construction worker, chef, and teacher, misleadingly implying that the drug would  
17 provide long-term pain-relief and functional improvement. Upon information and  
18 belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in  
19 2012 in medical journals. These ads featured chronic pain patients and  
20 recommended OxyContin for each. One ad described a "54-year-old writer with  
21 osteoarthritis of the hands" and implied that OxyContin would help the writer  
22 work more effectively.

23 92. Second, each Manufacturer Defendant promoted the use of opioids  
24 for chronic pain through "detailers" – sales representatives who visited individual  
25 doctors and medical staff in their offices – and small-group speaker programs. The  
26 Manufacturer Defendants have not corrected this misinformation. Instead, each  
27 Defendant devoted massive resources to direct sales contacts with doctors. Upon  
28 information and belief, in 2014 alone, the Manufacturer Defendants spent in

1 excess of \$168 million on detailing branded opioids to doctors, more than twice  
2 what they spent on detailing in 2000.

3 93. The Manufacturer Defendants' detailing to doctors is effective.  
4 Numerous studies indicate that marketing impacts prescribing habits, with face-to-  
5 face detailing having the greatest influence. Even without such studies, the  
6 Manufacturer Defendants purchase, manipulate and analyze some of the most  
7 sophisticated data available in any industry, data available from IMS Health  
8 Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by  
9 individual doctor, which in turn allows them to target, tailor, and monitor the  
10 impact of their core messages. Thus, the Manufacturer Defendants know their  
11 detailing to doctors is effective.

12 94. The Manufacturer Defendants' detailers have been reprimanded for  
13 their deceptive promotions. In March 2010, for example, the FDA found that  
14 Actavis had been distributing promotional materials that "minimize[] the risks  
15 associated with Kadian and misleadingly suggest[] that Kadian is safer than has  
16 been demonstrated." Those materials in particular "fail to reveal warnings  
17 regarding potentially fatal abuse of opioids, use by individuals other than the  
18 patient for whom the drug was prescribed."<sup>79</sup>

19 **b) Indirect Marketing.**

20 95. The Manufacturer Defendants indirectly marketed their opioids using  
21 unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and  
22 industry-funded organizations posing as neutral and credible professional societies  
23 and patient advocacy groups (referred to hereinafter as "Front Groups").

24 96. The Manufacturer Defendants deceptively marketed opioids in the  
25 State and Plaintiffs' Community through unbranded advertising – e.g., advertising  
26

27 <sup>79</sup> Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns,  
28 U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb.  
18, 2010),  
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

1 that promotes opioid use generally but does not name a specific opioid. This  
2 advertising was ostensibly created and disseminated by independent third parties.  
3 But by funding, directing, reviewing, editing, and distributing this unbranded  
4 advertising, the Manufacturer Defendants controlled the deceptive messages  
5 disseminated by these third parties and acted in concert with them to falsely and  
6 misleadingly promote opioids for the treatment of chronic pain. Much as  
7 Defendants controlled the distribution of their “core messages” via their own  
8 detailers and speaker programs, the Manufacturer Defendants similarly controlled  
9 the distribution of these messages in scientific publications, treatment guidelines,  
10 Continuing Medical Education (“CME”) programs, and medical conferences and  
11 seminars. To this end, the Manufacturer Defendants used third-party public  
12 relations firms to help control those messages when they originated from third-  
13 parties.

14 97. The Manufacturer Defendants marketed through third-party,  
15 unbranded advertising to avoid regulatory scrutiny because that advertising is not  
16 submitted to and typically is not reviewed by the FDA. The Manufacturer  
17 Defendants also used third-party, unbranded advertising to give the false  
18 appearance that the deceptive messages came from an independent and objective  
19 source. Like the tobacco companies, the Manufacturer Defendants used third  
20 parties that they funded, directed, and controlled to carry out and conceal their  
21 scheme to deceive doctors and patients about the risks and benefits of long term  
22 opioid use for chronic pain.

23 98. Defendants also identified doctors to serve, for payment, on their  
24 speakers’ bureaus and to attend programs with speakers and meals paid for by  
25 Defendants. These speaker programs provided: (1) an incentive for doctors to  
26 prescribe a particular opioid (so they might be selected to promote the drug); (2)  
27 recognition and compensation for the doctors selected as speakers; and (3) an  
28 opportunity to promote the drug through the speaker to his or her peers. These

1 speakers give the false impression that they are providing unbiased and medically  
2 accurate presentations when they are, in fact, presenting a script prepared by  
3 Defendants. On information and belief, these presentations conveyed misleading  
4 information, omitted material information, and failed to correct Defendants' prior  
5 misrepresentations about the risks and benefits of opioids.

6 99. Borrowing a page from Big Tobacco's playbook, the Manufacturer  
7 Defendants worked through third parties they controlled by: (a) funding, assisting,  
8 encouraging, and directing doctors who served as KOLS, and (b) funding,  
9 assisting, directing, and encouraging seemingly neutral and credible Front Groups.  
10 The Manufacturer Defendants then worked together with those KOLs and Front  
11 Groups to taint the sources that doctors and patients relied on for ostensibly  
12 "neutral" guidance, such as treatment guidelines, CME programs, medical  
13 conferences and seminars, and scientific articles. Thus, working individually and  
14 collectively, and through these Front Groups and KOLs, the Manufacturer  
15 Defendants persuaded doctors and patients that what they have long known – that  
16 opioids are addictive drugs, unsafe in most circumstances for long-term use – was  
17 untrue, and that the compassionate treatment of pain required opioids.

18 100. In 2007, multiple States sued Purdue for engaging in unfair and  
19 deceptive practices in its marketing, promotion, and sale of OxyContin. Certain  
20 states settled their claims in a series of Consent Judgments that prohibited Purdue  
21 from making misrepresentations in the promotion and marketing of OxyContin in  
22 the future. By using indirect marketing strategies, however, Purdue intentionally  
23 circumvented these restrictions. Such actions include contributing to the creation  
24 of misleading publications and prescribing guidelines which lack reliable  
25 scientific basis, and promoting prescribing practices which have worsened the  
26 opioid crisis.

27 101. Pro-opioid doctors are one of the most important avenues that the  
28 Manufacturer Defendants use to spread their false and deceptive statements about

1 the risks and benefits of long-term opioid use. The Manufacturer Defendants  
2 know that doctors rely heavily and less critically on their peers for guidance, and  
3 KOLs provide the false appearance of unbiased and reliable support for chronic  
4 opioid therapy. For example, the State of New York found in its settlement with  
5 Purdue that the Purdue website “In the Face of Pain” failed to disclose that doctors  
6 who provided testimonials on the site were paid by Purdue and concluded that  
7 Purdue’s failure to disclose these financial connections potentially misled  
8 consumers regarding the objectivity of the testimonials.

9 102. Defendants utilized many KOLs, including many of the same ones.

10 103. Dr. Russell Portenoy, former Chairman of the Department of Pain  
11 Medicine and Palliative Care at Beth Israel Medical Center in New York, is one  
12 example of a KOL whom the Manufacturer Defendants identified and promoted to  
13 further their marketing campaign. Dr. Portenoy received research support,  
14 consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among  
15 others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was  
16 instrumental in opening the door for the regular use of opioids to treat chronic  
17 pain. He served on the American Pain Society (“APS”) / American Academy of  
18 Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of  
19 opioids to treat chronic pain, first in 1996 and again in 2009. He was also a  
20 member of the board of the American Pain Foundation (“APF”), an advocacy  
21 organization almost entirely funded by the Manufacturer Defendants.

22 104. Dr. Portenoy also made frequent media appearances promoting  
23 opioids and spreading misrepresentations, such as his claim that “the likelihood  
24 that the treatment of pain using an opioid drug which is prescribed by a doctor  
25 will lead to addiction is extremely low.” He appeared on Good Morning America  
26 in 2010 to discuss the use of opioids long-term to treat chronic pain. On this  
27 widely-watched program, broadcast across the country, Dr. Portenoy claimed:  
28 “Addiction, when treating pain, is distinctly uncommon. If a person does not have

1 a history, a personal history, of substance abuse, and does not have a history in the  
 2 family of substance abuse, and does not have a very major psychiatric disorder,  
 3 most doctors can feel very assured that that person is not going to become  
 4 addicted.”<sup>80</sup>

5 105. Dr. Portenoy later admitted that he “gave innumerable lectures in the  
 6 late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely  
 7 claimed that fewer than 1% of patients would become addicted to opioids.  
 8 According to Dr. Portenoy, because the primary goal was to “destigmatize”  
 9 opioids, he and other doctors promoting them overstated their benefits and glossed  
 10 over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of  
 11 opioids does not exist.”<sup>81</sup> Portenoy candidly stated: “Did I teach about pain  
 12 management, specifically about opioid therapy, in a way that reflects  
 13 misinformation? Well, . . . I guess I did.”<sup>82</sup>

14 106. Another KOL, Dr. Lynn Webster, was the co-founder and Chief  
 15 Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic  
 16 in Salt Lake City, Utah. Dr. Webster was President of the AAPM in 2013. He is a  
 17 Senior Editor of Pain Medicine, the same journal that published Endo special  
 18 advertising supplements touting Opana ER. Dr. Webster was the author of  
 19 numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time,  
 20 Dr. Webster was receiving significant funding from the Manufacturer Defendants  
 21 (including nearly \$2 million from Cephalon).

22 107. During a portion of his time as a KOL, Dr. Webster was under  
 23 investigation for overprescribing by the U.S. Department of Justice’s Drug  
 24

25 <sup>80</sup> Good Morning America (ABC television broadcast Aug. 30, 2010).

26 <sup>81</sup> Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*,  
 27 Wall St. J., Dec. 17, 2012,  
 28 [https://www.wsj.com/articles/SB1000142412788732447830457817334265704460](https://www.wsj.com/articles/SB10001424127887324478304578173342657044604)  
 4.

<sup>82</sup> *Id.*



1 Enforcement Agency, which raided his clinic in 2010. Although the investigation  
 2 was closed without charges in 2014, more than 20 of Dr. Webster's former  
 3 patients at the Lifetree Clinic have died of opioid overdoses.

4 108. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a  
 5 five question, one-minute screening tool relying on patient self-reports that  
 6 purportedly allows doctors to manage the risk that their patients will become  
 7 addicted to or abuse opioids. The claimed ability to pre-sort patients likely to  
 8 become addicted is an important tool in giving doctors confidence to prescribe  
 9 opioids long-term, and for this reason, references to screening appear in various  
 10 industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear  
 11 on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the  
 12 flawed science and industry bias underlying this tool, certain states and public  
 13 entities have incorporated the Opioid Risk Tool into their own guidelines,  
 14 indicating, also, their reliance on the Manufacturer Defendants and those under  
 15 their influence and control.

16 109. In 2011, Dr. Webster presented, via webinar, a program sponsored by  
 17 Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the  
 18 Risk." Dr. Webster recommended use of risk screening tools, urine testing, and  
 19 patient agreements as a way to prevent "overuse of prescriptions" and "overdose  
 20 deaths." This webinar was available to and was intended to reach doctors in the  
 21 State and doctors treating members of Plaintiffs' Community.<sup>83</sup>

22 110. Dr. Webster also was a leading proponent of the concept of  
 23 "pseudoaddiction," the notion that addictive behaviors should be seen not as  
 24 warnings, but as indications of undertreated pain. In Dr. Webster's description, the  
 25 only way to differentiate the two was to increase a patient's dose of opioids. As he  
 26

27 <sup>83</sup> See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the*  
 28 *Need and the Risk*, [http://www.emergingsolutionsinpain.com/ce-education/opioid-](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=20)  
 management?option=com\_continued&view=frontmatter&Itemid=303&course=20  
 9 (last visited Aug. 22, 2017).



1 and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While*  
 2 *Managing Pain*—a book that is still available online—when faced with signs of  
 3 aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s  
 4 first response.”<sup>84</sup> Upon information and belief, Endo distributed this book to  
 5 doctors. Years later, Dr. Webster reversed himself, acknowledging that  
 6 “[pseudoaddiction] obviously became too much of an excuse to give patients more  
 7 medication.”<sup>85</sup>

8 111. The Manufacturer Defendants also entered into arrangements with  
 9 seemingly unbiased and independent patient and professional organizations to  
 10 promote opioids for the treatment of chronic pain. Under the direction and control  
 11 of the Manufacturer Defendants, these “Front Groups” generated treatment  
 12 guidelines, unbranded materials, and programs that favored chronic opioid  
 13 therapy. They also assisted the Manufacturer Defendants by responding to  
 14 negative articles, by advocating against regulatory changes that would limit opioid  
 15 prescribing in accordance with the scientific evidence, and by conducting outreach  
 16 to vulnerable patient populations targeted by the Manufacturer Defendants.

17 112. These Front Groups depended on the Manufacturer Defendants for  
 18 funding and, in some cases, for survival. The Manufacturer Defendants also  
 19 exercised control over programs and materials created by these groups by  
 20 collaborating on, editing, and approving their content, and by funding their  
 21 dissemination. In doing so, the Manufacturer Defendants made sure that the Front  
 22 Groups would generate only the messages that the Manufacturer Defendants  
 23 wanted to distribute. Despite this, the Front Groups held themselves out as  
 24

25  
 26 <sup>84</sup> Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

27 <sup>85</sup> John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J.  
 28 Sentinel, Feb. 18, 2012,  
<http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

1 independent and serving the needs of their members – whether patients suffering  
2 from pain or doctors treating those patients.

3 113. Defendants Cephalon, Endo, Janssen, and Purdue, in particular,  
4 utilized many Front Groups, including many of the same ones. Several of the most  
5 prominent are described below, but there are many others, including the American  
6 Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of  
7 State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”),  
8 the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and  
9 Pain & Policy Studies Group (“PPSG”).<sup>86</sup>

10 114. The most prominent of the Manufacturer Defendants’ Front Groups  
11 was the American Pain Foundation (“APF”), which, upon information and belief,  
12 received more than \$10 million in funding from opioid manufacturers from 2007  
13 until it closed its doors in May 2012, primarily from Endo and Purdue. APF  
14 issued education guides for patients, reporters, and policymakers that touted the  
15 benefits of opioids for chronic pain and trivialized their risks, particularly the risk  
16 of addiction. APF also launched a campaign to promote opioids for returning  
17 veterans, which has contributed to high rates of addiction and other adverse  
18 outcomes – including death – among returning soldiers. APF also engaged in a  
19 significant multimedia campaign – through radio, television and the internet – to  
20 educate patients about their “right” to pain treatment, namely opioids. All of the  
21 programs and materials were available nationally and were intended to reach  
22 citizens of the State and Plaintiffs’ Community.

23 115. In 2009 and 2010, more than 80% of APF’s operating budget came  
24 from pharmaceutical industry sources. Including industry grants for specific  
25

26 <sup>86</sup> See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to  
27 Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015),  
28 <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

1 projects, APF received about \$2.3 million from industry sources out of total  
2 income of about \$2.85 million in 2009; its budget for 2010 projected receipts of  
3 roughly \$2.9 million from drug companies, out of total income of about \$3.5  
4 million. By 2011, upon information and belief, APF was entirely dependent on  
5 incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid  
6 using its line of credit.

7 116. APF held itself out as an independent patient advocacy organization.  
8 It often engaged in grassroots lobbying against various legislative initiatives that  
9 might limit opioid prescribing, and thus the profitability of its sponsors. Upon  
10 information and belief, it was often called upon to provide “patient  
11 representatives” for the Manufacturer Defendants’ promotional activities,  
12 including for Purdue’s Partners Against Pain and Janssen’s Let’s Talk Pain. APF  
13 functioned largely as an advocate for the interests of the Manufacturer  
14 Defendants, not patients. Indeed, upon information and belief, as early as 2001,  
15 Purdue told APF that the basis of a grant was Purdue’s desire to “strategically  
16 align its investments in nonprofit organizations that share [its] business interests.”

17 117. Plaintiffs are informed and believe that on several occasions,  
18 representatives of the Manufacturer Defendants, often at informal meetings at  
19 conferences, suggested activities and publications for APF to pursue. APF then  
20 submitted grant proposals seeking to fund these activities and publications,  
21 knowing that drug companies would support projects conceived as a result of  
22 these communications.

23 118. The U.S. Senate Finance Committee began looking into APF in May  
24 2012 to determine the links, financial and otherwise, between the organization and  
25 the manufacturers of opioid painkillers. The investigation caused considerable  
26 damage to APF’s credibility as an objective and neutral third party, and the  
27 Manufacturer Defendants stopped funding it. Within days of being targeted by  
28 Senate investigation, APF’s board voted to dissolve the organization “due to

1 irreparable economic circumstances.” APF “cease[d] to exist, effective  
2 immediately.”<sup>87</sup>

3 119. Another front group for the Manufacturer Defendants was the  
4 American Academy of Pain Medicine (“AAPM”). With the assistance, prompting,  
5 involvement, and funding of the Manufacturer Defendants, the AAPM issued  
6 purported treatment guidelines and sponsored and hosted medical education  
7 programs essential to the Manufacturer Defendants’ deceptive marketing of  
8 chronic opioid therapy.

9 120. AAPM received substantial funding from opioid manufacturers. For  
10 example, AAPM maintained a corporate relations council, whose members paid  
11 \$25,000 per year (on top of other funding) to participate. The benefits included  
12 allowing members to present educational programs at off-site dinner symposia in  
13 connection with AAPM’s marquee event – its annual meeting held in Palm  
14 Springs, California, or other resort locations. AAPM describes the annual event as  
15 an “exclusive venue” for offering education programs to doctors. Membership in  
16 the corporate relations council also allows drug company executives and  
17 marketing staff to meet with AAPM executive committee members in small  
18 settings. Defendants Endo, Purdue, and Cephalon were members of the council  
19 and presented deceptive programs to doctors who attended this annual event.

20 121. Upon information and belief, AAPM is viewed internally by Endo as  
21 “industry friendly,” with Endo advisors and speakers among its active members.  
22 Endo attended AAPM conferences, funded its CMEs, and distributed its  
23 publications. The conferences sponsored by AAPM heavily emphasized sessions  
24 on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents  
25

26 <sup>87</sup> Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies’*  
27 *Ties to Pain Groups*, Wash. Post, May 8, 2012,  
28 [https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU\\_story.html](https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html).

1 have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr.  
2 Webster was even elected president of AAPM while under a DEA investigation.

3 122. The Manufacturer Defendants were able to influence AAPM through  
4 both their significant and regular funding and the leadership of pro-opioid KOLs  
5 within the organization.

6 123. In 1996, AAPM and APS jointly issued a consensus statement, “The  
7 Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to  
8 treat chronic pain and claimed that the risk of a patients’ addiction to opioids was  
9 low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker  
10 for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus  
11 statement remained on AAPM’s website until 2011, and, upon information and  
12 belief, was taken down from AAPM’s website only after a doctor complained.<sup>88</sup>

13 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS  
14 Guidelines”) and continued to recommend the use of opioids to treat chronic  
15 pain.<sup>89</sup> Treatment guidelines have been relied upon by doctors, especially the  
16 general practitioners and family doctors targeted by the Manufacturer Defendants.  
17 Treatment guidelines not only directly inform doctors’ prescribing practices, but  
18 are cited throughout the scientific literature and referenced by third-party payors  
19 in determining whether they should cover treatments for specific indications.  
20 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue  
21 discussed treatment guidelines with doctors during individual sales visits.

22 125. At least fourteen of the 21 panel members who drafted the  
23 AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the  
24 University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

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26 <sup>88</sup> The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement  
27 From the American Academy of Pain Medicine and the American Pain Society, 13  
Clinical J. Pain 6 (1997).

28 <sup>89</sup> Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in  
Chronic Non-Cancer Pain, 10 J. Pain 113 (2009).

1 The 2009 Guidelines promote opioids as “safe and effective” for treating chronic  
2 pain, despite acknowledging limited evidence, and conclude that the risk of  
3 addiction is manageable for patients regardless of past abuse histories.<sup>90</sup> One  
4 panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State  
5 University and founder of the Michigan Headache & Neurological Institute,  
6 resigned from the panel because of his concerns that the 2009 Guidelines were  
7 influenced by contributions that drug companies, including Manufacturer  
8 Defendants, made to the sponsoring organizations and committee members. These  
9 AAPM/APS Guidelines have been a particularly effective channel of deception  
10 and have influenced not only treating physicians, but also the body of scientific  
11 evidence on opioids; the Guidelines have been cited hundreds of times in  
12 academic literature, were disseminated in the State and/or Plaintiffs’ Community  
13 during the relevant time period, are still available online, and were reprinted in the  
14 Journal of Pain. The Manufacturer Defendants widely referenced and promoted  
15 the 2009 Guidelines without disclosing the lack of evidence to support them or the  
16 Manufacturer Defendants’ financial support to members of the panel.

17 126. The Manufacturer Defendants worked together, through Front  
18 Groups, to spread their deceptive messages about the risks and benefits of long-  
19 term opioid therapy. For example, Defendants combined their efforts through the  
20 Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is  
21 comprised of representatives from opioid manufacturers (including Cephalon,  
22 Endo, Janssen, and Purdue) and various Front Groups, almost all of which  
23 received substantial funding from the Manufacturer Defendants. Among other  
24 projects, PCF worked to ensure that an FDA-mandated education project on  
25 opioids was not unacceptably negative and did not require mandatory participation  
26  
27

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28 <sup>90</sup> *Id.*



1 by prescribers, which the Manufacturer Defendants determined would reduce  
2 prescribing.

3 **2. The Manufacturer Defendants' Marketing Scheme**

4 **Misrepresented the Risks and Benefits of Opioids.**

5 **i. The Manufacturer Defendants embarked upon a campaign**  
6 **of false, deceptive, and unfair assurances grossly**  
7 **understating and misstating the dangerous addiction risks**  
8 **of the opioid drugs.**

9 127. To falsely assure physicians and patients that opioids are safe, the  
10 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of  
11 long-term opioid use, particularly the risk of addiction, through a series of  
12 misrepresentations that have been conclusively debunked by the FDA and CDC.  
13 These misrepresentations – which are described below – reinforced each other and  
14 created the dangerously misleading impression that: (1) starting patients on  
15 opioids was low risk because most patients would not become addicted, and  
16 because those at greatest risk for addiction could be identified and managed; (2)  
17 patients who displayed signs of addiction probably were not addicted and, in any  
18 event, could easily be weaned from the drugs; (3) the use of higher opioid doses,  
19 which many patients need to sustain pain relief as they develop tolerance to the  
20 drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent  
21 abuse and overdose and are inherently less addictive. The Manufacturer  
22 Defendants have not only failed to correct these misrepresentations, they continue  
23 to make them today.

24 128. Opioid manufacturers, including Defendants Endo Pharmaceuticals,  
25 Inc. and Purdue Pharma L.P., have entered into settlement agreements with public  
26 entities that prohibit them from making many of the misrepresentations identified  
27 in this Complaint. Yet even afterward, each Manufacturer Defendant continued to  
28 misrepresent the risks and benefits of long-term opioid use in the State and  
Plaintiffs' Community and each continues to fail to correct its past  
misrepresentations.



1 129. Some illustrative examples of the Manufacturer Defendants' false,  
2 deceptive, and unfair claims about the purportedly low risk of addiction include:

- 3 a. Actavis's predecessor caused a patient education brochure, *Managing*  
4 *Chronic Back Pain*, to be distributed beginning in 2003 that admitted  
5 that opioid addiction is possible, but falsely claimed that it is "less  
6 likely if you have never had an addiction problem." Based on  
7 Actavis's acquisition of its predecessor's marketing materials along  
8 with the rights to Kadian, it appears that Actavis continued to use this  
9 brochure in 2009 and beyond.
- 10 b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide*  
11 *for People Living with Pain* (2007), which suggested that addiction is  
12 rare and limited to extreme cases of unauthorized dose escalations,  
13 obtaining duplicative opioid prescriptions from multiple sources, or  
14 theft. This publication is still available online.<sup>91</sup>
- 15 c. Endo sponsored a website, "PainKnowledge," which, upon  
16 information and belief, claimed in 2009 that "[p]eople who take  
17 opioids as prescribed usually do not become addicted." Upon  
18 information and belief, another Endo website, PainAction.com, stated  
19 "Did you know? Most chronic pain patients do not become addicted  
20 to the opioid medications that are prescribed for them." Endo also  
21 distributed an "Informed Consent" document on PainAction.com that  
22 misleadingly suggested that only people who "have problems with  
23 substance abuse and addiction" are likely to become addicted to  
24 opioid medications.
- 25 d. Upon information and belief, Endo distributed a pamphlet with the  
26 Endo logo entitled *Living with Someone with Chronic Pain*, which  
27 stated that: "Most health care providers who treat people with pain  
28 agree that most people do not develop an addiction problem."
- 29 e. Janssen reviewed, edited, approved, and distributed a patient  
30 education guide entitled *Finding Relief: Pain Management for Older*  
31 *Adults* (2009), which described as "myth" the claim that opioids are  
32 addictive, and asserted as fact that "[m]any studies show that opioids  
33 are rarely addictive when used properly for the management of  
34 chronic pain."
- 35 f. Janssen currently runs a website, Prescriberresponsibly.com (last  
36 updated July 2, 2015), which claims that concerns about opioid  
37 addiction are "overestimated."
- 38 g. Purdue sponsored APF's *A Policymaker's Guide to Understanding*  
39 *Pain & Its Management*, which claims that less than 1% of children

91 Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007)  
[hereinafter APF, *Treatment Options*],  
<https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”<sup>92</sup>

- h. In 2010, Mallinckrodt sponsored an initiative “Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book “Defeat Chronic Pain Now!” aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at [www.defeatchronicpainnow.com](http://www.defeatchronicpainnow.com), advises laypeople who are considering taking opioid drugs that “[o]nly rarely does opioid medication cause a true addiction.”<sup>93</sup> Further, the book advises that even the issue of tolerance is “overblown,” because “[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance.” In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that “[i]t is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- i. Consistent with the Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiffs’ Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.<sup>94</sup>

130. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that there is “[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .).”<sup>95</sup> The 2016 CDC Guideline further explains that “[o]pioid pain

<sup>92</sup> Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

<sup>93</sup> Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010).

<sup>94</sup> Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

<sup>95</sup> Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at

1 medication use presents serious risks, including overdose and opioid use disorder”  
 2 and that “continuing opioid therapy for 3 months substantially increases risk for  
 3 opioid use disorder.”<sup>96</sup>

4 131. The FDA further exposed the falsity of Defendants’ claims about the  
 5 low risk of addiction when it announced changes to the labels for extended-release  
 6 and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs  
 7 have ‘high potential for abuse’” and that opioids “are associated with a substantial  
 8 risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction,  
 9 overdose, and death.” According to the FDA, because of the “known serious  
 10 risks” associated with long-term opioid use, including “risks of addiction, abuse,  
 11 and misuse, even at recommended doses, and because of the greater risks of  
 12 overdose and death,” opioids should be used only “in patients for whom  
 13 alternative treatment options” like non-opioid drugs have failed.<sup>97</sup>

15 132. The State of New York, in a 2016 settlement agreement with Endo,  
 16 found that opioid “use disorders appear to be highly prevalent in chronic pain  
 17 patients treated with opioids, with up to 40% of chronic pain patients treated in  
 18 specialty and primary care outpatient centers meeting the clinical criteria for an

19  
 20  
 21  
 22 15 [hereinafter 2016 CDC Guideline],  
<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

23 <sup>96</sup> *Id.* at 2, 25.

24 <sup>97</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and  
 25 Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to  
 26 Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing  
 27 (Sept. 10, 2013), <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf>; Letter from Janet  
 28 Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and  
 Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers &  
 Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016),  
<https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf>.

1 opioid use disorder.”<sup>98</sup> Endo had claimed on its www.opana.com website that  
 2 “[m]ost healthcare providers who treat patients with pain agree that patients  
 3 treated with prolonged opioid medicines usually do not become addicted,” but the  
 4 State of New York found that Endo had no evidence for that statement. Consistent  
 5 with this, Endo agreed not to “make statements that . . . opioids generally are non-  
 6 addictive” or “that most patients who take opioids do not become addicted” in  
 7 New York. Endo remains free, however, to make those statements in this State.

8 133. In addition to mischaracterizing the highly addictive nature of the  
 9 drugs they were pushing, the Manufacturer Defendants also fostered a  
 10 fundamental misunderstanding of the signs of addiction. Specifically, the  
 11 Manufacturer Defendants misrepresented, to doctors and patients, that warning  
 12 signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e.  
 13 pseudoaddiction) – and instructed doctors to increase the opioid prescription dose  
 14 for patients who were already in danger.

15 134. To this end, one of Purdue’s employees, Dr. David Haddox, invented  
 16 a phenomenon called “pseudoaddiction.” KOL Dr. Portenoy popularized the term.  
 17 Examples of the false, misleading, deceptive, and unfair statements regarding  
 18 pseudoaddiction include:

- 19 a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing*  
 20 (2007), which taught that behaviors such as “requesting drugs by  
 21 name,” “demanding or manipulative behavior,” seeing more than one  
 22 doctor to obtain opioids, and hoarding, are all signs of  
 23 pseudoaddiction, rather than true addiction.<sup>99</sup> The 2012 edition,  
 24 which remains available for sale online, continues to teach that  
 25 pseudoaddiction is real.<sup>100</sup>

25 <sup>98</sup> Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo*  
 26 *Pharm. Inc.* (Assurance No. 15-228), at 16,  
[https://ag.ny.gov/pdfs/Endo\\_AOD\\_030116-Fully\\_Executed.pdf](https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

27 <sup>99</sup> Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide*  
 (2007) at 62.

28 <sup>100</sup> See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s*  
*Guide* (2d ed. 2012).

- b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.
- f. In 2010, Mallinckrodt sponsored an initiative "Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which is still available for sale, and is promoted online at [www.defeatchronicpainnow.com](http://www.defeatchronicpainnow.com), teaches laypeople that "pseudoaddiction" is "caused by their doctor not appropriately prescribing the opioid medication." It teaches that "[p]seudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or if the drug is not being prescribed often enough throughout the day. . . . When a pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn't take any extra pills because his or her pain is relieved."

135. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

136. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening



1 tools, patient contracts, urine drug screens, and similar strategies allow them to  
 2 reliably identify and safely prescribe opioids to patients predisposed to addiction.  
 3 These misrepresentations were especially insidious because the Manufacturer  
 4 Defendants aimed them at general practitioners and family doctors who lack the  
 5 time and expertise to closely manage higher-risk patients on opioids. The  
 6 Manufacturer Defendants' misrepresentations made these doctors feel more  
 7 comfortable prescribing opioids to their patients, and patients more comfortable  
 8 starting on opioid therapy for chronic pain. Illustrative examples include:

- 9 a. Endo paid for a 2007 supplement in the *Journal of Family Practice*  
 10 written by a doctor who became a member of Endo's speakers bureau  
 11 in 2010. The supplement, entitled *Pain Management Dilemmas in*  
 12 *Primary Care: Use of Opioids*, emphasized the effectiveness of  
 screening tools, claiming that patients at high risk of addiction could  
 safely receive chronic opioid therapy using a "maximally structured  
 approach" involving toxicology screens and pill counts.
- 13 b. Purdue, upon information and belief, sponsored a 2011 webinar,  
 14 *Managing Patient's Opioid Use: Balancing the Need and Risk*, which  
 15 claimed that screening tools, urine tests, and patient agreements  
 prevent "overuse of prescriptions" and "overdose deaths."
- 16 c. As recently as 2015, upon information and belief, Purdue has  
 17 represented in scientific conferences that "bad apple" patients – and  
 18 not opioids – are the source of the addiction crisis and that once those  
 "bad apples" are identified, doctors can safely prescribe opioids  
 without causing addiction.

19 137. The 2016 CDC Guideline confirms the falsity of these claims. The  
 20 Guideline explains that there are no studies assessing the effectiveness of risk  
 21 mitigation strategies "for improving outcomes related to overdose, addiction,  
 22 abuse or misuse."<sup>101</sup>

23 138. A fourth category of deceptive messaging regarding dangerous  
 24 opioids is the Manufacturer Defendants' false assurances regarding the alleged  
 25 ease of eliminating opioid dependence. The Manufacturer Defendants falsely  
 26 claimed that opioid dependence can easily be addressed by tapering and that  
 27 opioid withdrawal is not a problem, but they failed to disclose the increased

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28 <sup>101</sup> *Id.* at 11.

1 difficulty of stopping opioids after long-term use. In truth, the 2016 CDC  
 2 Guideline explains that the symptoms of opioid withdrawal include abdominal  
 3 pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety,  
 4 insomnia, spontaneous abortion and premature labor in pregnant women.<sup>102</sup>

5 139. The Manufacturer Defendants nonetheless downplayed the severity  
 6 of opioid detoxification. For example, upon information and belief, a CME  
 7 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that  
 8 withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-  
 9 20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to*  
 10 *Understanding Pain & Its Management*, which claimed that "[s]ymptoms of  
 11 physical dependence can often be ameliorated by gradually decreasing the dose of  
 12 medication during discontinuation" without mentioning any hardships that might  
 13 occur.<sup>103</sup> Similarly, in the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat  
 14 Chronic Pain Now!" potential opioid users are advised that tolerance to opioids is  
 15 "easily remedied," and that "[a]ll patients can be safely taken off opioid  
 16 medication if the dose is slowly tapered down by their doctor."

17 140. A fifth category of false, deceptive, and unfair statements the  
 18 Manufacturer Defendants made to sell more drugs is that opioid dosages could be  
 19 increased indefinitely without added risk. The ability to escalate dosages was  
 20 critical to Defendants' efforts to market opioids for long-term use to treat chronic  
 21 pain because, absent this misrepresentation, doctors would have abandoned  
 22 treatment when patients built up tolerance and lower dosages did not provide pain  
 23 relief. The Manufacturer Defendants' deceptive claims include:

24  
 25  
 26 <sup>102</sup> *Id.* at 26.

27 <sup>103</sup> Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its*  
 28 *Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*],  
<http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 32.



- a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.<sup>104</sup> This publication is still available online.
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."<sup>105</sup>
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.<sup>106</sup>

<sup>104</sup> Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>, at 12.

<sup>105</sup> Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

<sup>106</sup> Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*],

- h. In 2007, Purdue sponsored a CME entitled “Overview of Management Options” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that Non-steroidal Anti-inflammatory Drugs (“NSAIDs”) and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.<sup>107</sup>
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.<sup>108</sup>
- k. In the 2010 Mallinckrodt/C.A.R.E.S. publication “Defeat Chronic Pain Now!”, potential opioid users are warned about the risk of “[p]seudoaddiction [b]ecause of a [l]ow [d]ose,” and advised that this condition may be corrected through the prescription of a higher dose. Similarly, the book recommends that for chronic pain patients, the opioid dose should be “gradually increased to find the best daily dose, as is done with all the other oral drugs.” The book discusses the risks of NSAIDs and other drugs at higher doses, but not explain this risk for opioids.

141. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants’ representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”<sup>109</sup> More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.”<sup>110</sup> The CDC also states that

<http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 32.

<sup>107</sup> The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited Aug. 21, 2017).

<sup>108</sup> Brief of APF, at 9.

<sup>109</sup> 2016 CDC Guideline at 22–23.

<sup>110</sup> *Id.* at 23–24.

1 there is an increased risk “for opioid use disorder, respiratory depression, and  
 2 death at higher dosages.”<sup>111</sup> That is why the CDC advises doctors to “avoid  
 3 increasing dosage” to above 90 morphine milligram equivalents per day.<sup>112</sup>

4 142. Defendants’ deceptive marketing of the so-called abuse-deterrent  
 5 properties of some of their opioids has created false impressions that these opioids  
 6 can cure addiction and abuse.

7 143. The Manufacturer Defendants made misleading claims about the  
 8 ability of their so-called abuse-deterrent opioid formulations to deter abuse. For  
 9 example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed  
 10 that it was designed to be crush resistant, in a way that suggested it was more  
 11 difficult to abuse. This claim was false. The FDA warned in a 2013 letter that  
 12 Opana ER Extended-Release Tablets’ “extended-release features can be  
 13 compromised, causing the medication to ‘dose dump,’ when subject to . . . forms  
 14 of manipulation such as cutting, grinding, or chewing, followed by  
 15 swallowing.”<sup>113</sup> Also troubling, Opana ER can be prepared for snorting using  
 16 commonly available methods and “readily prepared for injection.”<sup>114</sup> The letter  
 17 discussed “the troubling possibility that a higher (and rising) percentage of [Opana  
 18 ER Extended-Release Tablet] abuse is occurring via injection.”<sup>115</sup> Endo’s own  
 19 studies, which it failed to disclose, showed that Opana ER could still be ground  
 20 and chewed. In June 2017, the FDA requested that Opana ER be removed from  
 21 the market.

22 **ii. The Manufacturer Defendants embarked upon a**  
 23 **campaign of false, deceptive, and unfair assurances**

24 <sup>111</sup> *Id.* at 21.

25 <sup>112</sup> *Id.* at 16.

26 <sup>113</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and  
 27 Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to  
 Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

28 <sup>114</sup> *Id.* at 6.

<sup>115</sup> *Id.* at 6 n.21.

**grossly overstating the benefits of the opioid drugs.**

144. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials  $\leq$  6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.<sup>116</sup> The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

145. Some illustrative examples of the Manufacturer Defendants’ false claims are:

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors’ offices, of presumed patients in active professions; the caption read, “Pain doesn’t fit into their schedules.”
- e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions

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<sup>116</sup> *Id.* at 15.

1 persisting over several months and recommending OxyContin for  
2 them. The ads implied that OxyContin improves patients' function.

- 3 f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by  
4 Cephalon, Endo and Purdue, taught that relief of pain by opioids, by  
5 itself, improved patients' function.
- 6 g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide*  
7 *for People Living with Pain* (2007), which counseled patients that  
8 opioids "give [pain patients] a quality of life we deserve."<sup>117</sup> This  
9 publication is still available online.
- 10 h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon  
11 information and belief, that with opioids, "your level of function  
12 should improve; you may find you are now able to participate in  
13 activities of daily living, such as work and hobbies, that you were not  
14 able to enjoy when your pain was worse." Elsewhere, the website  
15 touted improved quality of life (as well as "improved function") as  
16 benefits of opioid therapy. The grant request that Endo approved for  
17 this project specifically indicated NIPC's intent to make misleading  
18 claims about function, and Endo closely tracked visits to the site.
- 19 i. Endo was the sole sponsor, through NIPC, of a series of CMEs  
20 entitled "Persistent Pain in the Older Patient."<sup>118</sup> Upon information  
21 and belief, a CME disseminated via webcast claimed that chronic  
22 opioid therapy has been "shown to reduce pain and improve  
23 depressive symptoms and cognitive functioning."
- 24 j. Janssen sponsored and funded a multimedia patient education  
25 campaign called "Let's Talk Pain." One feature of the campaign was  
26 to complain that patients were under-treated. In 2009, upon  
27 information and belief, a Janssen-sponsored website, part of the  
28 "Let's Talk Pain" campaign, featured an interview edited by Janssen  
claiming that opioids allowed a patient to "continue to function."
- k. Purdue sponsored the development and distribution of APF's *A*  
*Policymaker's Guide to Understanding Pain & Its Management*,  
which claimed that "[m]ultiple clinical studies" have shown that  
opioids are effective in improving "[d]aily function,"  
"[p]sychological health," and "[o]verall health-related quality of life  
for chronic pain."<sup>119</sup> The Policymaker's Guide was originally  
published in 2011.

<sup>117</sup> Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007)  
[hereinafter APF, *Treatment Options*],  
<https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

<sup>118</sup> E.g., NIPC, *Persistent Pain and the Older Patient* (2007),  
[https://www.painedu.org/Downloads/NIPC/Activities/B173\\_Providence\\_RI\\_%20Invited.pdf](https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invited.pdf).

<sup>119</sup> Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its*  
*Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*],  
<http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at  
29.



1. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

146. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

147. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."<sup>120</sup> And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

148. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and immediate-release ("IR") opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line

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<sup>120</sup> Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

1 treatment for chronic pain, particularly arthritis and lower back pain.<sup>121</sup> Purdue  
2 misleadingly promoted OxyContin as being unique among opioids in providing 12  
3 continuous hours of pain relief with one dose. In fact, OxyContin does not last for  
4 12 hours – a fact that Purdue has known at all times relevant to this action. Upon  
5 information and belief, Purdue’s own research shows that OxyContin wears off in  
6 under six hours in one quarter of patients and in under 10 hours in more than half.  
7 This is because OxyContin tablets release approximately 40% of their active  
8 medicine immediately, after which release tapers. This triggers a powerful initial  
9 response, but provides little or no pain relief at the end of the dosing period, when  
10 less medicine is released. This phenomenon is known as “end of dose” failure, and  
11 the FDA found in 2008 that a “substantial proportion” of chronic pain patients  
12 taking OxyContin experience it. This not only renders Purdue’s promise of 12  
13 hours of relief false and deceptive, it also makes OxyContin more dangerous  
14 because the declining pain relief patients experience toward the end of each  
15 dosing period drives them to take more OxyContin before the next dosing period  
16 begins, quickly increasing the amount of drug they are taking and spurring  
17 growing dependence.

18 149. Purdue’s competitors were aware of this problem. For example, upon  
19 information and belief, Endo ran advertisements for Opana ER referring to “real”  
20 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were  
21 effective for a full 12 hours. Upon information and belief, Purdue’s sales  
22 representatives continue to tell doctors that OxyContin lasts a full 12 hours.

23 150. Front Groups supported by Purdue likewise echoed these  
24 representations. For example, in an amicus brief submitted to the Supreme Court  
25 of Ohio by the American Pain Foundation, the National Foundation for the  
26

27  
28 <sup>121</sup> 2016 CDC Guideline at 12.



1 Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici  
2 represented:

3 OxyContin is particularly useful for sustained long-term pain because  
4 it comes in higher, compact pills with a slow release coating.  
5 OxyContin pills can work for 12 hours. This makes it easier for  
6 patients to comply with dosing requirements without experiencing a  
7 roller-coaster of pain relief followed quickly by pain renewal that can  
8 occur with shorter acting medications. It also helps the patient sleep  
9 through the night, which is often impossible with short-acting  
10 medications. For many of those serviced by Pain Care Amici,  
11 OxyContin has been a miracle medication.<sup>122</sup>

12 151. Cephalon deceptively marketed its opioids Actiq and Fentora for  
13 chronic pain even though the FDA has expressly limited their use to the treatment  
14 of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are  
15 extremely powerful fentanyl-based IR opioids. Neither is approved for or has been  
16 shown to be safe or effective for chronic pain. Indeed, the FDA expressly  
17 prohibited Cephalon from marketing Actiq for anything but cancer pain, and  
18 refused to approve Fentora for the treatment of chronic pain because of the  
19 potential harm, including the high risk of “serious and life-threatening adverse  
20 events” and abuse – which are greatest in non-cancer patients. The FDA also  
21 issued a Public Health Advisory in 2007 emphasizing that Fentora should only be  
22 used for cancer patients who are opioid-tolerant and should not be used for any  
23 other conditions, such as migraines, post-operative pain, or pain due to injury.<sup>123</sup>  
24 Specifically, the FDA advised that Fentora “is only approved for breakthrough

25 <sup>122</sup> Reply Brief of Amicus Curiae of the American Pain Foundation, The National  
26 Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting  
27 Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13,  
28 2004), 2004 WL 1637768, at \*4 (footnote omitted).

<sup>123</sup> See U.S. Food & Drug Admin., *Public Health Advisory: Important Information  
for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007),  
<https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

1 cancer pain in patients who are *opioid-tolerant*, meaning those patients who take a  
2 regular, daily, around-the-clock narcotic pain medication.”<sup>124</sup>

3 152. Despite this, Cephalon conducted and continues to conduct a well-  
4 funded campaign to promote Actiq and Fentora for chronic pain and other non-  
5 cancer conditions for which it was not approved, appropriate, and for which it is  
6 not safe. As part of this campaign, Cephalon used CMEs, speaker programs,  
7 KOLs, journal supplements, and detailing by its sales representatives to give  
8 doctors the false impression that Actiq and Fentora are safe and effective for  
9 treating non-cancer pain. For example:

- 10 a. Cephalon paid to have a CME it sponsored, *Opioid-Based*  
11 *Management of Persistent and Breakthrough Pain*, published in a  
12 supplement of Pain Medicine News in 2009. The CME instructed  
13 doctors that “[c]linically, broad classification of pain syndromes as  
14 either cancer- or non-cancer-related has limited utility” and  
15 recommended Actiq and Fentora for patients with chronic pain.
- 16 b. Upon information and belief, Cephalon’s sales representatives set up  
17 hundreds of speaker programs for doctors, including many non-  
18 oncologists, which promoted Actiq and Fentora for the treatment of  
19 non-cancer pain.
- 20 c. In December 2011, Cephalon widely disseminated a journal  
21 supplement entitled “Special Report: An Integrated Risk Evaluation  
22 and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and  
23 Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology  
24 News, Clinical Oncology News, and Pain Medicine News – three  
25 publications that are sent to thousands of anesthesiologists and other  
26 medical professionals. The Special Report openly promotes Fentora  
27 for “multiple causes of pain” – and not just cancer pain.

21 153. Cephalon’s deceptive marketing gave doctors and patients the false  
22 impression that Actiq and Fentora were not only safe and effective for treating  
23 chronic pain, but were also approved by the FDA for such uses.

24 154. Purdue also unlawfully and unfairly failed to report or address illicit  
25 and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s  
26 sales representatives have maintained a database since 2002 of doctors suspected  
27

28 <sup>124</sup> *Id.*

1 of inappropriately prescribing its drugs. Rather than report these doctors to state  
2 medical boards or law enforcement authorities (as Purdue is legally obligated to  
3 do) or cease marketing to them, Purdue used the list to demonstrate the high rate  
4 of diversion of OxyContin – the same OxyContin that Purdue had promoted as  
5 less addictive – in order to persuade the FDA to bar the manufacture and sale of  
6 generic copies of the drug because the drug was too likely to be abused. In an  
7 interview with the Los Angeles Times, Purdue’s senior compliance officer  
8 acknowledged that in five years of investigating suspicious pharmacies, Purdue  
9 failed to take action – even where Purdue employees personally witnessed the  
10 diversion of its drugs. The same was true of prescribers; despite its knowledge of  
11 illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed  
12 more than 1.1 million OxyContin tablets and that Purdue’s district manager  
13 described it internally as “an organized drug ring” until years after law  
14 enforcement shut it down. In doing so, Purdue protected its own profits at the  
15 expense of public health and safety.<sup>125</sup>

16 155. Like Purdue, Endo has been cited for its failure to set up an effective  
17 system for identifying and reporting suspicious prescribing. In its settlement  
18 agreement with Endo, the State of New York found that Endo failed to require  
19 sales representatives to report signs of abuse, diversion, and inappropriate  
20 prescribing; paid bonuses to sales representatives for detailing prescribers who  
21 were subsequently arrested or convicted for illegal prescribing; and failed to  
22 prevent sales representatives from visiting prescribers whose suspicious conduct  
23 had caused them to be placed on a no-call list.

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27 <sup>125</sup> Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the*  
28 *Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10,  
2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

1                   **3. The Manufacturer Defendants Targeted Susceptible Prescribers**  
 2                   **and Vulnerable Patient Populations.**

3           156. As a part of their deceptive marketing scheme, the Manufacturer  
 4 Defendants identified and targeted susceptible prescribers and vulnerable patient  
 5 populations in the U.S., including this State and Plaintiffs' Community. For  
 6 example, the Manufacturer Defendants focused their deceptive marketing on  
 7 primary care doctors, who were more likely to treat chronic pain patients and  
 8 prescribe them drugs, but were less likely to be educated about treating pain and  
 9 the risks and benefits of opioids and therefore more likely to accept the  
 10 Manufacturer Defendants' misrepresentations.

11           157. The Manufacturer Defendants also targeted vulnerable patient  
 12 populations like the elderly and veterans, who tend to suffer from chronic pain.  
 13 The Manufacturer Defendants targeted these vulnerable patients even though the  
 14 risks of long-term opioid use were significantly greater for them. For example, the  
 15 2016 CDC Guideline observes that existing evidence confirms that elderly  
 16 patients taking opioids suffer from elevated fall and fracture risks, reduced renal  
 17 function and medication clearance, and a smaller window between safe and unsafe  
 18 dosages.<sup>126</sup> The 2016 CDC Guideline concludes that there must be "additional  
 19 caution and increased monitoring" to minimize the risks of opioid use in elderly  
 20 patients. *Id.* at 27. The same is true for veterans, who are more likely to use anti-  
 21 anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact  
 22 dangerously with opioids.

23                   **4. Insys Employed Fraudulent, Illegal, and Misleading Marketing**  
 24                   **Schemes to Promote Subsys.**

25           158. Insys's opioid, Subsys, was approved by the FDA in 2012 for  
 26 "management of breakthrough pain in adult cancer patients who are already  
 27

28                   

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<sup>126</sup> 2016 CDC Guideline at 13.

1 receiving and who are tolerant to around-the-clock opioid therapy for their  
 2 underlying persistent cancer pain.” Under FDA rules, Insys could only market  
 3 Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl,  
 4 administered via a sublingual (under the tongue) spray, which provides rapid-  
 5 onset pain relief. It is in the class of drugs described as Transmucosal Immediate-  
 6 Release Fentanyl (“TIRF”).

7 159. To reduce the risk of abuse, misuse, and diversion, the FDA  
 8 instituted a Risk Evaluation and Mitigation Strategy (“REMS”) for Subsys and  
 9 other TIRF products, such as Cephalon’s Actiq and Fentora. The purpose of  
 10 REMS was to educate “prescribers, pharmacists, and patients on the potential for  
 11 misuse, abuse, addiction, and overdose” for this type of drug and to “ensure safe  
 12 use and access to these drugs for patients who need them.”<sup>127</sup> Prescribers must  
 13 enroll in the TIRF REMS before writing a prescription for Subsys.

14 160. Since its launch, Subsys has been an extremely expensive  
 15 medication, and its price continues to rise each year. Depending on a patient’s  
 16 dosage and frequency of use, a month’s supply of Subsys could cost in the  
 17 thousands of dollars.

18 161. Due to its high cost, in most instances prescribers must submit  
 19 Subsys prescriptions to insurance companies or health benefit payors for prior  
 20 authorization to determine whether they will pay for the drug prior to the patient  
 21 attempting to fill the prescription. According to the U.S. Senate Homeland  
 22 Security and Governmental Affairs Committee Minority Staff Report (“Staff  
 23 Report”), the prior authorization process includes “confirmation that the patient  
 24 had an active cancer diagnosis, was being treated by an opioid (and, thus, was  
 25 opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that  
 26

27  
 28 <sup>127</sup> Press Release, FDA, *FDA Approves Shared System REMS for TIRF Products*,  
 Dec. 29, 2011.

1 the other opioid could not eliminate. If any one of these factors was not present,  
 2 the prior authorization would be denied . . . .”<sup>128</sup>

3 162. These prior authorization requirements proved to be daunting.  
 4 Subsys received reimbursement approval in only approximately 30% of submitted  
 5 claims. In order to increase approvals, Insys created a prior authorization unit,  
 6 called the Insys Reimbursement Center (“IRC”), to obtain approval for Subsys  
 7 reimbursements. This unit employed a number of fraudulent and misleading  
 8 tactics to secure reimbursements, including falsifying medical histories of  
 9 patients, falsely claiming that patients had cancer, and providing misleading  
 10 information to insurers and payors regarding patients’ diagnoses and medical  
 11 conditions.

12 163. Subsys has proved to be extremely profitable for Insys. Insys made  
 13 approximately \$330 million in net revenue from Subsys last year. Between 2013  
 14 and 2016, the value of Insys stock rose 296%.

15 164. Since its launch in 2012, Insys aggressively worked to grow its  
 16 profits through fraudulent, illegal, and misleading tactics, including its  
 17 reimbursement-related fraud. Through its sales representatives and other  
 18 marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for  
 19 uses such as neck and back pain, without disclosing the lack of approval or  
 20 evidence for such uses, and misrepresented the appropriateness of Subsys for  
 21 treatment those conditions. It implemented a kickback scheme wherein it paid  
 22 prescribers for fake speakers programs in exchange for prescribing Subsys. All of  
 23 these fraudulent and misleading schemes had the effect of pushing Insys’s  
 24 dangerous opioid onto patients who did not need it.

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 27 <sup>128</sup> U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling*  
 28 *an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior*  
*Authorization*, <https://www.documentcloud.org/documents/3987564-REPORT-Fueling-an-Epidemic-Insys-Therapeutics.html>.



1           165. Insys incentivized its sales force to engage in illegal and fraudulent  
 2 conduct. Many of the Insys sales representatives were new to the pharmaceutical  
 3 industry and their base salaries were low compared to industry standard. The  
 4 compensation structure was heavily weighted toward commissions and rewarded  
 5 reps more for selling higher (and more expensive) doses of Subsys, a “highly  
 6 unusual” practice because most companies consider dosing a patient-specific  
 7 decision that should be made by a doctor.<sup>129</sup>

8           166. The Insys “speakers program” was perhaps its most widespread and  
 9 damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam  
 10 action that the sole purpose of the speakers program was “in the words of his then  
 11 supervisor Alec Burlakoff, ‘to get money in the doctor’s pocket.’” Furchak went  
 12 on to explain that “[t]he catch . . . was that doctors who increased the level of  
 13 Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms  
 14 instead of 200 micrograms), would receive the invitations to the program—and  
 15 the checks.”<sup>130</sup> It was a pay-to-prescribe program.

16           167. Insys’s sham speaker program and other fraudulent and illegal tactics  
 17 have been outlined in great detail in indictments and guilty pleas of Insys  
 18 executives, employees, and prescribers across the country, as well as in a number  
 19 of lawsuits against the company itself.

20           168. In May of 2015, two Alabama pain specialists were arrested and  
 21 charged with illegal prescription drug distribution, among other charges. The  
 22 doctors were the top prescribers of Subsys, though neither were oncologists.  
 23 According to prosecutors, the doctors received illegal kickbacks from Insys for  
 24 prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and  
 25 joint pain. In February of 2016, a former Insys sales manager pled guilty to  
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27 <sup>129</sup> *Id.*

28 <sup>130</sup> Roddy Boyd, *Insys Therapeutics and the New ‘Killing It’*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015.

1 conspiracy to commit health care fraud, including engaging in a kickback scheme  
2 in order to induce one of these doctors to prescribe Subsys. The plea agreement  
3 states that nearly all of the Subsys prescriptions written by the doctor were off-  
4 label to non-cancer patients. In May of 2017, one of the doctors was sentenced to  
5 20 years in prison.

6 169. In June of 2015, a nurse practitioner in Connecticut described as the  
7 state's highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000  
8 in kickbacks from Insys for prescribing Subsys. Most of her patients were  
9 prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more  
10 than 70 dinner programs at approximately \$1,000 per event; however, she did not  
11 give any presentations. In her guilty plea, the nurse admitted receiving the  
12 speaker fees in exchange for writing prescriptions for Subsys.

13 170. In August of 2015, Insys settled a complaint brought by the Oregon  
14 Attorney General. In its complaint, the Oregon Department of Justice cited Insys  
15 for, among other things, misrepresenting to doctors that Subsys could be used to  
16 treat migraine, neck pain, back pain, and other uses for which Subsys is neither  
17 safe nor effective, and using speaking fees as kickbacks to incentivize doctors to  
18 prescribe Subsys.

19 171. In August of 2016, the State of Illinois sued Insys for similar  
20 deceptive and illegal practices. The Complaint alleged that Insys marketed  
21 Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose  
22 patients experienced the breakthrough cancer pain for which the drug is indicated.  
23 The Illinois Complaint also details how Insys used its speaker program to pay  
24 high volume prescribers to prescribe Subsys. The speaker events took place at  
25 upscale restaurants in the Chicago area, and Illinois speakers received an  
26 "honorarium" ranging from \$700 to \$5,100, and they were allowed to order as  
27 much food and alcohol as they wanted. At most of the events, the "speaker" being  
28

1 paid by Insys did not speak, and, on many occasions, the only attendees at the  
2 events were the speaker and an Insys sales representative.

3 172. In December of 2016, six Insys executives and managers were  
4 indicted and then, in October 2017, Insys's founder and owner was arrested and  
5 charged with multiple felonies in connection with an alleged conspiracy to bribe  
6 practitioners to prescribe Subsys and defraud insurance companies. A U.S.  
7 Department of Justice press release explained that, among other things: "Insys  
8 executives improperly influenced health care providers to prescribe a powerful  
9 opioid for patients who did not need it, and without complying with FDA  
10 requirements, thus putting patients at risk and contributing to the current opioid  
11 crisis."<sup>131</sup> A Drug Enforcement Administration ("DEA") Special Agent in Charge  
12 further explained that: "Pharmaceutical companies whose products include  
13 controlled medications that can lead to addiction and overdose have a special  
14 obligation to operate in a trustworthy, transparent manner, because their  
15 customers' health and safety and, indeed, very lives depend on it."<sup>132</sup>

## 16 **5. The Manufacturer Defendants made Materially Deceptive** 17 **Statements and Concealed Material Facts.**

18 173. As alleged herein, the Manufacturer Defendants made and/or  
19 disseminated deceptive statements regarding material facts and further concealed  
20 material facts, in the course of manufacturing, marketing, and selling prescription  
21 opioids. The Manufacturer Defendants' actions were intentional and/or unlawful.  
22 Such statements include, but are not limited to, those set out below and alleged  
23 throughout this Complaint.

26 <sup>131</sup> Press Release, DOJ, U.S. Attorney's Office, Dist. of Mass., *Founder and Owner*  
27 *of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct.  
28 26, 2017), available at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

<sup>132</sup> *Id.*

1           174. Defendant Purdue made and/or disseminated deceptive statements,  
2 and concealed material facts in such a way to make their statements deceptive,  
3 including, but not limited to, the following:

- 4           a. Creating, sponsoring, and assisting in the distribution of patient  
5 education materials distributed to consumers that contained deceptive  
6 statements;
- 7           b. Creating and disseminating advertisements that contained deceptive  
8 statements concerning the ability of opioids to improve function  
9 long-term and concerning the evidence supporting the efficacy of  
10 opioids long-term for the treatment of chronic non-cancer pain;
- 11           c. Disseminating misleading statements concealing the true risk of  
12 addiction and promoting the deceptive concept of pseudoaddiction  
13 through Purdue's own unbranded publications and on internet sites  
14 Purdue operated that were marketed to and accessible by consumers;
- 15           d. Distributing brochures to doctors, patients, and law enforcement  
16 officials that included deceptive statements concerning the indicators  
17 of possible opioid abuse;
- 18           e. Sponsoring, directly distributing, and assisting in the distribution of  
19 publications that promoted the deceptive concept of pseudoaddiction,  
20 even for high-risk patients;
- 21           f. Endorsing, directly distributing, and assisting in the distribution of  
22 publications that presented an unbalanced treatment of the long-term  
23 and dose-dependent risks of opioids versus NSAIDs;
- 24           g. Providing significant financial support to pro-opioid KOL doctors  
25 who made deceptive statements concerning the use of opioids to treat  
26 chronic non-cancer pain;
- 27           h. Providing needed financial support to pro-opioid pain organizations  
28 that made deceptive statements, including in patient education  
materials, concerning the use of opioids to treat chronic non-cancer  
pain;
- i. Assisting in the distribution of guidelines that contained deceptive  
statements concerning the use of opioids to treat chronic non-cancer  
pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing  
deceptive statements concerning the use of opioids to treat chronic  
non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly  
concluded opioids are safe and effective for the long-term treatment  
of chronic non-cancer pain and that opioids improve quality of life,  
while concealing contrary data;

1. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

175. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction

1 through Endo's own unbranded publications and on internet sites  
2 Endo sponsored or operated;

- 3 f. Endorsing, directly distributing, and assisting in the distribution of  
4 publications that presented an unbalanced treatment of the long-term  
5 and dose-dependent risks of opioids versus NSAIDs;
- 6 g. Providing significant financial support to pro-opioid KOLs, who  
7 made deceptive statements concerning the use of opioids to treat  
8 chronic non-cancer pain;
- 9 h. Providing needed financial support to pro-opioid pain organizations –  
10 including over \$5 million to the organization responsible for many of  
11 the most egregious misrepresentations – that made deceptive  
12 statements, including in patient education materials, concerning the  
13 use of opioids to treat chronic non-cancer pain;
- 14 i. Targeting the elderly by assisting in the distribution of guidelines that  
15 contained deceptive statements concerning the use of opioids to treat  
16 chronic non-cancer pain and misrepresented the risks of opioid  
17 addiction in this population;
- 18 j. Endorsing and assisting in the distribution of CMEs containing  
19 deceptive statements concerning the use of opioids to treat chronic  
20 non-cancer pain;
- 21 k. Developing and disseminating scientific studies that deceptively  
22 concluded opioids are safe and effective for the long-term treatment  
23 of chronic non-cancer pain and that opioids improve quality of life,  
24 while concealing contrary data;
- 25 l. Directly distributing and assisting in the dissemination of literature  
26 written by pro-opioid KOLs that contained deceptive statements  
27 concerning the use of opioids to treat chronic non-cancer pain,  
28 including the concept of pseudoaddiction;
- 29 m. Creating, endorsing, and supporting the distribution of patient and  
30 prescriber education materials that misrepresented the data regarding  
31 the safety and efficacy of opioids for the long-term treatment of  
32 chronic non-cancer pain, including known rates of abuse and  
33 addiction and the lack of validation for long-term efficacy; and
- 34 n. Making deceptive statements concerning the use of opioids to treat  
35 chronic non-cancer pain to prescribers through in-person detailing.

36 176. Defendant Janssen made and/or disseminated deceptive statements,  
37 and concealed material facts in such a way to make their statements deceptive,  
38 including, but not limited to, the following:

- 39 a. Creating, sponsoring, and assisting in the distribution of patient  
40 education materials that contained deceptive statements;
- 41 b. Directly disseminating deceptive statements through internet sites  
42 over which Janssen exercised final editorial control and approval  
43 stating that opioids are safe and effective for the long-term treatment



- of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
  - d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
  - e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
  - f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
  - g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
  - h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
  - i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
  - j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
  - k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
  - l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

1 m. Targeting veterans by sponsoring and disseminating patient  
2 education marketing materials that contained deceptive statements  
concerning the use of opioids to treat chronic non-cancer pain; and

3 n. Making deceptive statements concerning the use of opioids to treat  
4 chronic non-cancer pain to prescribers through in-person detailing.

5 177. Defendant Cephalon made and/or disseminated untrue, false and  
6 deceptive statements, and concealed material facts in such a way to make their  
statements deceptive, including, but not limited to, the following:

7 a. Creating, sponsoring, and assisting in the distribution of patient  
8 education materials that contained deceptive statements;

9 b. Sponsoring and assisting in the distribution of publications that  
10 promoted the deceptive concept of pseudoaddiction, even for high-  
risk patients;

11 c. Providing significant financial support to pro-opioid KOL doctors  
12 who made deceptive statements concerning the use of opioids to treat  
chronic non-cancer pain and breakthrough chronic non-cancer pain;

13 d. Developing and disseminating scientific studies that deceptively  
14 concluded opioids are safe and effective for the long-term treatment  
of chronic non-cancer pain in conjunction with Cephalon's potent  
rapid-onset opioids;

15 e. Providing needed financial support to pro-opioid pain organizations  
16 that made deceptive statements, including in patient education  
materials, concerning the use of opioids to treat chronic non-cancer  
17 pain;

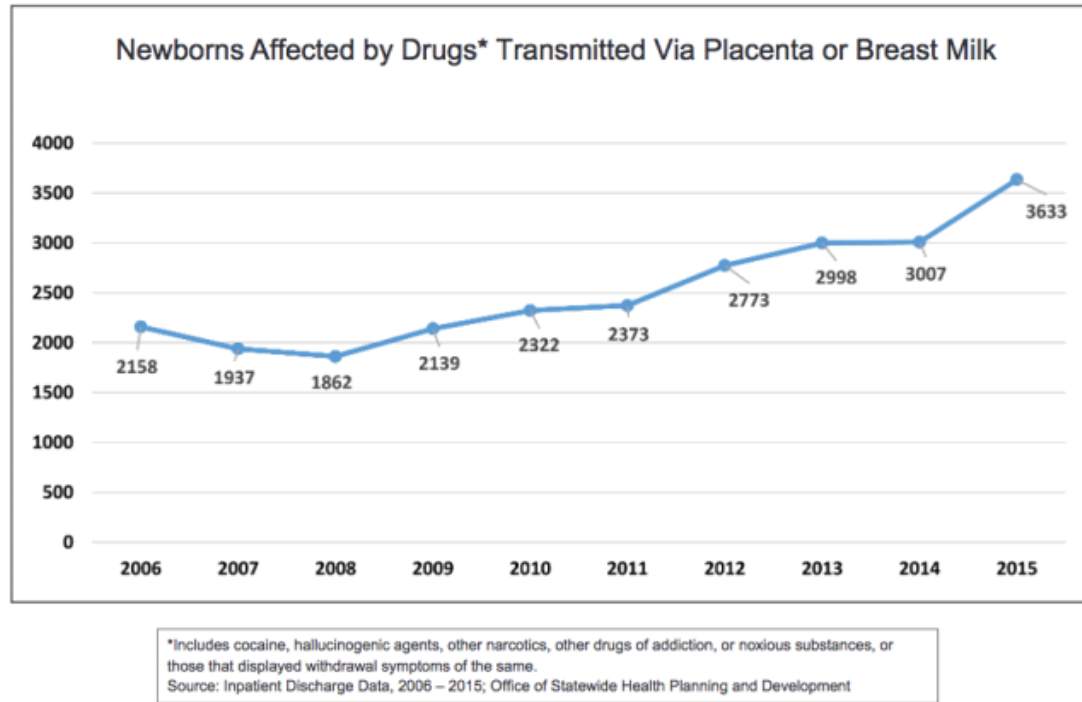
18 f. Endorsing and assisting in the distribution of CMEs containing  
19 deceptive statements concerning the use of opioids to treat chronic  
non-cancer pain;

20 g. Endorsing and assisting in the distribution of CMEs containing  
21 deceptive statements concerning the use of Cephalon's rapid-onset  
opioids;

22 h. Directing its marketing of Cephalon's rapid-onset opioids to a wide  
23 range of doctors, including general practitioners, neurologists, sports  
medicine specialists, and workers' compensation programs, serving  
chronic pain patients;

24 i. Making deceptive statements concerning the use of Cephalon's  
25 opioids to treat chronic non-cancer pain to prescribers through in-  
person detailing and speakers' bureau events, when such uses are  
unapproved and unsafe; and

26 j. Making deceptive statements concerning the use of opioids to treat  
27 chronic non-cancer pain to prescribers through in-person detailing  
and speakers' bureau events.  
28



178. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

#### **6. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.**

179. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as

1 research and clinical experience establish that opioids are highly addictive and are  
2 responsible for a long list of very serious adverse outcomes. The FDA warned  
3 Defendants of this, and Defendants had access to scientific studies, detailed  
4 prescription data, and reports of adverse events, including reports of addiction,  
5 hospitalization, and death – all of which clearly described the harm from long-  
6 term opioid use and that patients were suffering from addiction, overdose, and  
7 death in alarming numbers. More recently, the FDA and CDC have issued  
8 pronouncements, based on medical evidence, that conclusively expose the falsity  
9 of Defendants’ misrepresentations, and Endo and Purdue have recently entered  
10 into agreements in New York prohibiting them from making some of the same  
11 misrepresentations described in this Complaint.

12       180. At all times relevant to this Complaint, the Manufacturer Defendants  
13 took steps to avoid detection of and to fraudulently conceal their deceptive  
14 marketing and unlawful, unfair, and fraudulent conduct. For example, the  
15 Manufacturer Defendants disguised their role in the deceptive marketing of  
16 chronic opioid therapy by funding and working through third parties like Front  
17 Groups and KOLs. The Manufacturer Defendants purposefully hid behind the  
18 assumed credibility of these individuals and organizations and relied on them to  
19 vouch for the accuracy and integrity of the Manufacturer Defendants’ false and  
20 deceptive statements about the risks and benefits of long-term opioid use for  
21 chronic pain. Defendants also never disclosed their role in shaping, editing, and  
22 approving the content of information and materials disseminated by these third  
23 parties. The Manufacturer Defendants exerted considerable influence on these  
24 promotional and “educational” materials in emails, correspondence, and meetings  
25 with KOLs, Front Groups, and public relations companies that were not, and have  
26 not yet become, public. For example, PainKnowledge.org, which is run by the  
27 NIPC, did not disclose Endo’s involvement. Other Manufacturer Defendants, such  
28 as Purdue and Janssen, ran similar websites that masked their own role.

1           181. Finally, the Manufacturer Defendants manipulated their promotional  
 2 materials and the scientific literature to make it appear that these documents were  
 3 accurate, truthful, and supported by objective evidence when they were not. The  
 4 Manufacturer Defendants distorted the meaning or import of studies they cited  
 5 and offered them as evidence for propositions the studies did not support. The  
 6 Manufacturer Defendants invented “pseudoaddiction” and promoted it to an  
 7 unsuspecting medical community. The Manufacturer Defendants provided the  
 8 medical community with false and misleading information about ineffectual  
 9 strategies to avoid or control opioid addiction. The Manufacturer Defendants  
 10 recommended to the medical community that dosages be increased, without  
 11 disclosing the risks. The Manufacturer Defendants spent millions of dollars over a  
 12 period of years on a misinformation campaign aimed at highlighting opioids’  
 13 alleged benefits, disguising the risks, and promoting sales. The lack of support for  
 14 the Manufacturer Defendants’ deceptive messages was not apparent to medical  
 15 professionals who relied upon them in making treatment decisions, nor could it  
 16 have been detected by the Plaintiffs or Plaintiffs’ Community. Thus, the  
 17 Manufacturer Defendants successfully concealed from the medical community,  
 18 patients, and health care payors facts sufficient to arouse suspicion of the claims  
 19 that the Plaintiffs now assert. Plaintiffs did not know of the existence or scope of  
 20 the Manufacturer Defendants’ industry-wide fraud and could not have acquired  
 21 such knowledge earlier through the exercise of reasonable diligence.

22           **C. THE DISTRIBUTOR DEFENDANTS’ UNLAWFUL DISTRIBUTION**  
 23           **OF OPIOIDS.**

24           182. The Distributor Defendants owe a duty under both federal law (21  
 25 U.S.C. § 823, 21 CFR 1301.74) and California law (*see, e.g.*, Cal. Bus. & Prof.  
 26 Code § 4169.1) to monitor, detect, investigate, refuse to fill, and report suspicious  
 27 orders of prescription opioids originating from Plaintiffs’ Community as well as  
 28

1 those orders which the Distributor Defendants knew or should have known were  
2 likely to be diverted into Plaintiffs' Community.

3 183. The foreseeable harm from a breach of these duties is the diversion of  
4 prescription opioids for nonmedical purposes.

5 184. Each Distributor Defendant repeatedly and purposefully breached its  
6 duties under state and federal law. Such breaches are a direct and proximate cause  
7 of the widespread diversion of prescription opioids for nonmedical purposes into  
8 Plaintiffs' Community.

9 185. The unlawful diversion of prescription opioids is a direct and  
10 proximate cause and/or substantial contributing factor to the opioid epidemic,  
11 prescription opioid abuse, addiction, morbidity and mortality in the State and in  
12 Plaintiffs' Community. This diversion and the epidemic are direct causes of harms  
13 for which Plaintiffs seek to recover here.

14 186. The opioid epidemic in the State, including *inter alia* in Plaintiffs'  
15 Community, remains an immediate ***hazard to public health and safety***.

16 187. The opioid epidemic in Plaintiffs' Community is a temporary and  
17 continuous ***public nuisance*** and remains unabated.

18 188. The Distributor Defendants intentionally continued their conduct, as  
19 alleged herein, with knowledge that such conduct was creating the opioid nuisance  
20 and causing the harms and damages alleged herein.

21 **1. Wholesale Drug Distributors Have a Duty under State and**  
22 **Federal Law to Guard Against, and Report, Unlawful Diversion**  
23 **and to Report and Prevent Suspicious Orders.**

24 189. As under federal law, opioids are a Schedule II controlled substance  
25 under California law. *See* Cal. Health & Safety Code § 11055. Opioids are  
26 categorized as "Schedule II" drugs because they have a "high potential for abuse"  
27 and the potential to cause "severe psychic or physical dependence" and/or "severe  
28 psychological . . . dependence." 21 U.S.C. § 812(b)(2)(A)-(C).



1           190. California law required Distributor Defendants to be licensed by the  
2 California State Board of Pharmacy. Cal. Bus. & Prof. Code § 4160; Cal. Bus. &  
3 Prof. Code § 4161. California law required Manufacturer Defendants to be  
4 licensed by the State Department of Health Services. Cal. Health & Safety Code §  
5 111615.

6           191. The California State Board of Pharmacy has the authority to “deny,  
7 revoke, or suspend any license” issued to out-of-state manufacturers or wholesale  
8 distributors who violate the Pharmacy Law or the state’s Sherman Food, Drug and  
9 Cosmetic Law. Cal. Bus. & Prof. Code § 4304.

10           192. It is unlawful under California law for a distributor or manufacturer  
11 to “furnish controlled substances for other than legitimate medical purposes.” Cal.  
12 Health & Safety Code § 11153.5.

13           193. The California State Board of Pharmacy has the authority to “take  
14 action against any holder of a license who is guilty of unprofessional conduct”  
15 which includes “clearly excessive furnishing of controlled substances” for other  
16 than legitimate medical purposes. Cal. Bus. & Prof. Code § 4301(e) (citing Cal.  
17 Health & Safety Code § 11153.5). “Factors to be considered in determining  
18 whether the furnishing of controlled substances is clearly excessive shall include,  
19 but not be limited to, the amount of controlled substances furnished, the previous  
20 ordering pattern of the customer (including size and frequency of orders), the type  
21 and size of the customer, and where and to whom the customer distributes its  
22 product.” *Id.*

23           194. Other examples of unprofessional conduct include procuring a  
24 license by fraud or misrepresentation, gross negligence, fraud, making or signing  
25 documents with false statements, and violating any state or federal statute or rule  
26 regulating controlled substances. Cal. Bus. & Prof. Code § 4301.

27           195. California requires manufacturers and distributors of controlled  
28 substances to maintain records of the manufacture and sale of dangerous drugs.

1 *See* Cal. Bus. & Prof. Code §§ 4081; 4161(c)(2)(A); 4332; Cal. Code Regs. tit. 16,  
2 §§ 1780(f); 1783(e).

3 196. Furthermore, California law incorporates federal requirements set out  
4 under the Controlled Substance Act and related controlled substance laws and  
5 regulations. *See* Cal. Bus. & Prof. Code §§ 4160(d) (representative-in-charge of  
6 wholesaler is responsible for wholesaler's compliance with applicable state and  
7 federal laws); 4301(j) (unprofessional conduct includes violating federal laws  
8 related to controlled substances); 4301(o) (unprofessional conduct includes  
9 violating, attempting to violate, assisting in or abetting or conspiring to violate any  
10 applicable federal law); Cal. Code Regs. tit. 16, § 1780(f)(2) (records required for  
11 identifying, recording and reporting losses or thefts shall be in accordance with  
12 federal regulations).

13 197. Each Distributor Defendant was further required to register with the  
14 DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b),  
15 (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a  
16 wholesale distributor in the chain of distribution of Schedule II controlled  
17 substances with a duty to comply with all security requirements imposed under  
18 that statutory scheme. California law adopts and incorporates those requirements,  
19 as set out above. *See, e.g.,* Cal. Code Regs. tit. 16, 1780(f)(2).

20 198. Each Distributor Defendant has an affirmative duty under federal and  
21 California law to act as a gatekeeper guarding against the diversion of the highly  
22 addictive, dangerous opioid drugs. Federal law requires that Distributors of  
23 Schedule II drugs, including opioids, must maintain "effective control against  
24 diversion of particular controlled substances into other than legitimate medical,  
25 scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). California law  
26 requires that "[t]he following minimum standards shall apply to all wholesale  
27 establishments for which permits have been issued by the Board: . . . (c)(2) All  
28 facilities shall be equipped with a security system that will provide suitable

1 protection against theft and diversion.” Cal. Code Regs. Tit. 16 § 1780(c)(2). In  
 2 addition, drug distributors shall “establish, maintain, and adhere to written policies  
 3 and procedures, which shall be followed for the receipt, security, storage,  
 4 inventory, and distribution of prescription drugs, including policies and  
 5 procedures for identifying, recording, and reporting losses or thefts[.]” Cal. Code  
 6 Regs. Tit. 16 § 1780(f)(1).

7 199. The California Legislature has found that “Protection of the public  
 8 shall be the highest priority for the California State Board of Pharmacy in  
 9 exercising its licensing, regulatory, and disciplinary functions. Whenever the  
 10 protection of the public is inconsistent with other interests sought to be promoted,  
 11 the protection of the public shall be paramount.” Cal. Bus. & Prof. Code § 4001.1.

12 200. Federal regulations and California law impose a non-delegable duty  
 13 upon wholesale drug distributors to “design and operate a system to disclose to the  
 14 registrant suspicious orders of controlled substances. The registrant [distributor]  
 15 shall inform the Field Division Office of the Administration in his area of  
 16 suspicious orders when discovered by the registrant. Suspicious orders include  
 17 orders of unusual size, orders deviating substantially from a normal pattern, and  
 18 orders of unusual frequency.” 21 C.F.R. § 1301.74(b). *See also* Cal. Bus. & Prof.  
 19 Code § 4169.1 (“A wholesaler, upon discovery, shall notify the board in writing of  
 20 any suspicious orders of controlled substances placed by a California-licensed  
 21 pharmacy or wholesaler by providing the board a copy of the information that the  
 22 wholesaler provides to the United States Drug Enforcement Administration.”);  
 23 Cal. Health & Safety Code § 11153.5(c) (factors considered in determining if  
 24 distributor or manufacturer furnished controlled substances with a conscious  
 25 disregard that they were being used for other than legitimate medical purposes  
 26 include the amount of controlled substances furnished, the size and frequency of  
 27 previous orders, the type and size of customer and where the customer distributes  
 28 the product).

1           201. “Suspicious orders” include orders of an unusual size, orders of  
2 unusual frequency or orders deviating substantially from a normal pattern. *See* 21  
3 CFR 1301.74(b); *see also* Cal. Bus. & Prof. Code § 4169.1. These criteria are  
4 disjunctive and are not all inclusive. For example, if an order deviates  
5 substantially from a normal pattern, the size of the order does not matter and the  
6 order should be reported as suspicious. Likewise, a wholesale distributor need not  
7 wait for a normal pattern to develop over time before determining whether a  
8 particular order is suspicious. The size of an order alone, regardless of whether it  
9 deviates from a normal pattern, is enough to trigger the wholesale distributor’s  
10 responsibility to report the order as suspicious. The determination of whether an  
11 order is suspicious depends not only on the ordering patterns of the particular  
12 customer but also on the patterns of the entirety of the wholesale distributor’s  
13 customer base and the patterns throughout the relevant segment of the wholesale  
14 distributor industry.

15           202. In addition to reporting all suspicious orders, distributors must also  
16 stop shipment on any order which is flagged as suspicious and only ship orders  
17 which were flagged as potentially suspicious if, after conducting due diligence,  
18 the distributor can determine that the order is not likely to be diverted into illegal  
19 channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t  
20 Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement*  
21 *Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged  
22 orders must be reported. *Id.*

23           203. These prescription drugs are regulated for the purpose of providing a  
24 “closed” system **intended to reduce the widespread diversion of these drugs**  
25 **out of legitimate channels into the illicit market**, while at the same time  
26  
27  
28

1 providing the legitimate drug industry with a unified approach to narcotic and  
2 dangerous drug control.<sup>133</sup>

3 204. Different entities supervise the discrete links in the chain that  
4 separate a consumer from a controlled substance. Statutes and regulations define  
5 each participant's role and responsibilities.<sup>134</sup>

6 205. As the DEA advised the Distributor Defendants in a letter to them  
7 dated September 27, 2006, wholesale distributors are "one of the key components  
8 of the distribution chain. If the closed system is to function properly ...  
9 distributors must be vigilant in deciding whether a prospective customer can be  
10 trusted to deliver controlled substances only for lawful purposes. This  
11 responsibility is critical, as ... the illegal distribution of controlled substances has  
12 a substantial and detrimental effect on the health and general welfare of the  
13 American people."<sup>135</sup>

14  
15 <sup>133</sup> See 1970 U.S.C.C.A.N. 4566, 4571-72.

16 <sup>134</sup> Brief for Healthcare Distribution Management Association and National  
17 Association of Chain Drug Stores as Amici Curiae in Support of Neither Party,  
18 *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4,  
19 2016), 2016 WL 1321983, at \*22 [hereinafter Brief for HDMA and NACDS]. The  
20 Healthcare Distribution Management Association (HDMA or HMA)—now known  
21 as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade  
22 association that represents the nation's primary, full-service healthcare distributors  
23 whose membership includes, among others: AmerisourceBergen Drug  
24 Corporation, Cardinal Health, Inc., and McKesson Corporation. See generally  
25 HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited Aug. 21,  
26 2017). The National Association of Chain Drug Stores (NACDS) is a national,  
27 not-for-profit trade association that represents traditional drug stores and  
28 supermarkets and mass merchants with pharmacies whose membership includes,  
among others: Walgreen Company, CVS Health, Rite Aid Corporation and  
Walmart. See generally NACDS, *Mission*, <https://www.nacds.org/about/mission/>  
(last visited Aug. 21, 2017).

<sup>135</sup> See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of  
Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health  
(Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every  
commercial entity in the United States registered with the Drug Enforcement  
Agency (DEA) to distribute controlled substances. The purpose of this letter is to  
reiterate the responsibilities of controlled substance distributors in view of the  
prescription drug abuse problem our nation currently faces."), filed in *Cardinal  
Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No.  
14-51.

1           206. The Distributor Defendants have admitted that they are responsible  
2 for reporting suspicious orders.<sup>136</sup>

3           207. The DEA sent a letter to each of the Distributor Defendants on  
4 September 27, 2006, warning that it would use its authority to revoke and suspend  
5 registrations when appropriate. The letter expressly states that a distributor, *in*  
6 *addition* to reporting suspicious orders, has a “statutory responsibility to exercise  
7 due diligence to avoid filling suspicious orders that might be diverted into other  
8 than legitimate medical, scientific, and industrial channels.”<sup>137</sup> The letter also  
9 instructs that “distributors must be vigilant in deciding whether a prospective  
10 customer can be trusted to deliver controlled substances only for lawful  
11 purposes.”<sup>138</sup> The DEA warns that “even just one distributor that uses its DEA  
12 registration to facilitate diversion can cause enormous harm.”<sup>139</sup>

13           208. The DEA sent a second letter to each of the Distributor Defendants  
14 on December 27, 2007.<sup>140</sup> This letter reminds the Defendants of their statutory and  
15 regulatory duties to “maintain effective controls against diversion” and “design  
16 and operate a system to disclose to the registrant suspicious orders of controlled  
17 substances.”<sup>141</sup> The letter further explains:

18           The regulation also requires that the registrant inform the local DEA  
19 Division Office of suspicious orders when discovered by the  
20 registrant. Filing a monthly report of completed transactions (e.g.,

21 <sup>136</sup> See Brief for HDMA and NACDS, 2016 WL 1321983, at \*4  
22 (“[R]egulations . . . in place for more than 40 years require distributors to report  
23 suspicious orders of controlled substances to DEA based on information readily  
available to them (e.g., a pharmacy’s placement of unusually frequent or large  
orders).”).

24 <sup>137</sup> Rannazzisi Letter, at 2.

25 <sup>138</sup> *Id.* at 1.

26 <sup>139</sup> *Id.* at 2.

27 <sup>140</sup> See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of  
28 Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health  
(Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW  
(D.D.C. Feb. 10, 2012), ECF No. 14-8.

<sup>141</sup> *Id.*



1 “excessive purchase report” or “high unity purchases”) does not meet  
2 the regulatory requirement to report suspicious orders. Registrants are  
3 reminded that their responsibility does not end merely with the filing  
4 of a suspicious order report. Registrants must conduct an independent  
5 analysis of suspicious orders prior to completing a sale to determine  
6 whether the controlled substances are likely to be diverted from  
7 legitimate channels. Reporting an order as suspicious will not absolve  
8 the registrant of responsibility if the registrant knew, or should have  
9 known, that the controlled substances were being diverted.

10 The regulation specifically states that suspicious orders include orders  
11 of unusual size, orders deviating substantially from a normal pattern,  
12 and orders of an unusual frequency. These criteria are disjunctive and  
13 are not all inclusive. For example, if an order deviates substantially  
14 from a normal pattern, the size of the order does not matter and the  
15 order should be reported as suspicious. Likewise, a registrant need  
16 not wait for a “normal pattern” to develop over time before  
17 determining whether a particular order is suspicious. The size of an  
18 order alone, whether or not it deviates from a normal pattern, is  
19 enough to trigger the registrant’s responsibility to report the order as  
20 suspicious. The determination of whether an order is suspicious  
21 depends not only on the ordering patterns of the particular customer,  
22 but also on the patterns of the registrant’s customer base and the  
23 patterns throughout the segment of the regulated industry.

24 Registrants that rely on rigid formulas to define whether an order is  
25 suspicious may be failing to detect suspicious orders. For example, a  
26 system that identifies orders as suspicious only if the total amount of a  
27 controlled substance ordered during one month exceeds the amount  
28 ordered the previous month by a certain percentage or more is  
insufficient. This system fails to identify orders placed by a pharmacy  
if the pharmacy placed unusually large orders from the beginning of  
its relationship with the distributor. Also, this system would not  
identify orders as suspicious if the order were solely for one highly  
abused controlled substance if the orders never grew substantially.  
Nevertheless, ordering one highly abused controlled substance and  
little or nothing else deviates from the normal pattern of what  
pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in  
their communication with DEA that the registrant is actually  
characterizing an order as suspicious. Daily, weekly, or monthly  
reports submitted by registrant indicating “excessive purchases” do  
not comply with the requirement to report suspicious orders, even if  
the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these  
orders without first determining that order is not being diverted into  
other than legitimate medical, scientific, and industrial channels, may  
be failing to maintain effective controls against diversion. Failure to  
maintain effective controls against diversion is inconsistent with the  
public interest as that term is used in 21 USC 823 and 824, and may

1 result in the revocation of the registrant's DEA Certificate of  
Registration.<sup>142</sup>

2 Finally, the DEA letter references the Revocation of Registration issued in  
3 *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which  
4 discusses the obligation to report suspicious orders and "some criteria to use when  
5 determining whether an order is suspicious."<sup>143</sup>

6 209. The Distributor Defendants admit that they "have not only statutory  
7 and regulatory responsibilities to detect and prevent diversion of controlled  
8 prescription drugs, but undertake such efforts as responsible members of  
9 society."<sup>144</sup>

10 210. The Distributor Defendants knew they were required to monitor,  
11 detect, and halt suspicious orders. Industry compliance guidelines established by  
12 the Healthcare Distribution Management Association, the trade association of  
13 pharmaceutical distributors, explain that distributors are "[a]t the center of a  
14 sophisticated supply chain" and therefore "are uniquely situated to perform due  
15 diligence in order to help support the security of the controlled substances they  
16 deliver to their customers." The guidelines set forth recommended steps in the  
17 "due diligence" process, and note in particular: If an order meets or exceeds a  
18 distributor's threshold, as defined in the distributor's monitoring system, or is  
19 otherwise characterized by the distributor as an order of interest, the distributor  
20 should not ship to the customer, in fulfillment of that order, any units of the  
21 specific drug code product as to which the order met or exceeded a threshold or as  
22 to which the order was otherwise characterized as an order of interest.<sup>145</sup>

23  
24  
25 <sup>142</sup> *Id.*

26 <sup>143</sup> *Id.*

27 <sup>144</sup> See Brief of HDMA, 2012 WL 1637016, at \*2.

28 <sup>145</sup> Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

1           211. Each of the Distributor Defendants sold prescription opioids,  
2 including hydrocodone and/or oxycodone, to retailers in Plaintiffs' Community  
3 and/or to retailers from which Defendants knew prescription opioids were likely  
4 to be diverted to Plaintiffs' Community.

5           212. Each Distributor Defendant owes a duty to monitor and detect  
6 suspicious orders of prescription opioids.

7           213. Each Distributor Defendant owes a duty under federal and state law  
8 to investigate and refuse suspicious orders of prescription opioids.

9           214. Each Distributor Defendant owes a duty under federal and state law  
10 to report suspicious orders of prescription opioids.

11           215. Each Distributor Defendant owes a duty under federal and state law  
12 to prevent the diversion of prescription opioids into illicit markets in the State and  
13 Plaintiffs' Community.

14           216. The foreseeable harm resulting from a breach of these duties is the  
15 diversion of prescription opioids for nonmedical purposes and subsequent plague  
16 of opioid addiction.

17           217. The foreseeable harm resulting from the diversion of prescription  
18 opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in  
19 Plaintiffs' Community and the damages caused thereby.

20           **2. The Distributor Defendants Breached Their Duties.**

21           218. Because distributors handle such large volumes of controlled  
22 substances, and are the first major line of defense in the movement of legal  
23 pharmaceutical controlled substances from legitimate channels into the illicit  
24 market, it is incumbent on distributors to maintain effective controls to prevent  
25 diversion of controlled substances. Should a distributor deviate from these checks  
26 and balances, the closed system collapses.<sup>146</sup>

27  
28 <sup>146</sup> See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

1           219. The sheer volume of prescription opioids distributed to pharmacies in  
2 the Plaintiffs' Community, and/or to pharmacies from which the Distributor  
3 Defendants knew the opioids were likely to be diverted into Plaintiffs'  
4 Community, is excessive for the medical need of the community and facially  
5 suspicious. Some red flags are so obvious that no one who engages in the  
6 legitimate distribution of controlled substances can reasonably claim ignorance of  
7 them.<sup>147</sup>

8           220. The Distributor Defendants failed to report "suspicious orders"  
9 originating from Plaintiffs' Community, or which the Distributor Defendants  
10 knew were likely to be diverted to Plaintiffs' Community, to the federal and state  
11 authorities, including the DEA and/or the state Board of Pharmacy.

12           221. The Distributor Defendants unlawfully filled suspicious orders of  
13 unusual size, orders deviating substantially from a normal pattern and/or orders of  
14 unusual frequency in Plaintiffs' Community, and/or in areas from which the  
15 Distributor Defendants knew opioids were likely to be diverted to Plaintiffs'  
16 Community.

17           222. The Distributor Defendants breached their duty to monitor, detect,  
18 investigate, refuse and report suspicious orders of prescription opiates originating  
19 from Plaintiffs' Community, and/or in areas from which the Distributor  
20 Defendants knew opioids were likely to be diverted to Plaintiffs' Community.

21           223. The Distributor Defendants breached their duty to maintain effective  
22 controls against diversion of prescription opiates into other than legitimate  
23 medical, scientific, and industrial channels.

24           224. The Distributor Defendants breached their duty to "design and  
25 operate a system to disclose to the registrant suspicious orders of controlled  
26

27  
28 <sup>147</sup> *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015)  
(citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed.  
Reg. 62,316, 62,322 (2012)).

1 substances” and failed to inform the authorities including the DEA of suspicious  
2 orders when discovered, in violation of their duties under federal and state law.

3 225. The Distributor Defendants breached their duty to exercise due  
4 diligence to avoid filling suspicious orders that might be diverted into channels  
5 other than legitimate medical, scientific and industrial channels.<sup>148</sup>

6 226. The federal and state laws at issue here are public safety laws.

7 227. The Distributor Defendants’ violations of public safety statutes  
8 constitute prima facie evidence of negligence under State law.

9 228. The Distributor Defendants supplied prescription opioids to  
10 obviously suspicious physicians and pharmacies, enabled the illegal diversion of  
11 opioids, aided criminal activity, and disseminated massive quantities of  
12 prescription opioids into the black market.

13 229. The unlawful conduct by the Distributor Defendants is purposeful  
14 and intentional. The Distributor Defendants refuse to abide by the duties imposed  
15 by federal and state law which are required to legally acquire and maintain a  
16 license to distribute prescription opiates.

17 230. The Distributor Defendants acted with actual malice in breaching  
18 their duties, *i.e.*, they have acted with a conscious disregard for the rights and  
19 safety of other persons, and said actions have a great probability of causing  
20 substantial harm.

21 231. The Distributor Defendants’ repeated shipments of suspicious orders,  
22 over an extended period of time, in violation of public safety statutes, and without  
23 reporting the suspicious orders to the relevant authorities demonstrates wanton,  
24 willful, or reckless conduct or criminal indifference to civil obligations affecting  
25 the rights of others.

26  
27  
28 <sup>148</sup> See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

1                   **3. The Distributor Defendants Have Sought to Avoid and Have**  
 2                   **Misrepresented their Compliance with Their Legal Duties.**

3           232. The Distributor Defendants have repeatedly misrepresented their  
 4 compliance with their legal duties under state and federal law and have wrongfully  
 5 and repeatedly disavowed those duties in an effort to mislead regulators and the  
 6 public regarding the Distributor Defendants' compliance with their legal duties.

7           233. Distributor Defendants have refused to recognize any duty beyond  
 8 *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade  
 9 association run by the Distributor Defendants, and the NACDS submitted amicus  
 10 briefs regarding the legal duty of wholesale distributors. Inaccurately denying the  
 11 legal duties that the wholesale drug industry has been tragically recalcitrant in  
 12 performing, they argued as follows:

- 13           a. The Associations complained that the "DEA has required distributors  
 14 not only to report suspicious orders, but to *investigate* orders (e.g., by  
 15 interrogating pharmacies and physicians) and take action to *halt*  
 suspicious orders before they are filled."<sup>149</sup>
- 16           b. The Associations argued that, "DEA now appears to have changed its  
 17 position to require that distributors not only *report* suspicious orders,  
 18 but *investigate* and *halt* suspicious orders. Such a change in agency  
 19 position must be accompanied by an acknowledgment of the change  
 20 and a reasoned explanation for it. In other words, an agency must  
 display awareness that it *is* changing position and show that there are  
 good reasons for the new policy. This is especially important here,  
 because imposing intrusive obligations on distributors threatens to  
 disrupt patient access to needed prescription medications."<sup>150</sup>
- 21           c. The Associations alleged (inaccurately) that nothing "requires  
 22 distributors to investigate the legitimacy of orders, or to halt  
 shipment of any orders deemed to be suspicious."<sup>151</sup>
- 23           d. The Association complained that the purported "practical infeasibility  
 24 of requiring distributors to investigate and halt suspicious orders (as  
 25 well as report them) underscores the importance of ensuring that  
 DEA has complied with the APA before attempting to impose such  
 duties."<sup>152</sup>

26 <sup>149</sup> Brief for HDMA and NACDS, 2016 WL 1321983, at \*4–5.

27 <sup>150</sup> *Id.* at \*8 (citations and quotation marks omitted).

28 <sup>151</sup> *Id.* at \*14.

<sup>152</sup> *Id.* at \*22.



1 e. The Associations alleged (inaccurately) that “DEA’s regulations []  
2 sensibly impose[] a duty on distributors simply to *report* suspicious  
3 orders, but left it to DEA and its agents to investigate and halt  
4 suspicious orders.”<sup>153</sup>

5 f. Also inaccurately, the Associations argued that, “[i]mposing a duty  
6 on distributors – which lack the patient information and the necessary  
7 medical expertise – to investigate and halt orders may force  
8 distributors to take a shot-in-the-dark approach to complying with  
9 DEA’s demands.”<sup>154</sup>

10 234. The positions taken by the trade groups is emblematic of the position  
11 taken by the Distributor Defendants in a futile attempt to deny their legal  
12 obligations to prevent diversion of the dangerous drugs.<sup>155</sup>

13 235. The Court of Appeals for the District of Columbia recently issued its  
14 opinion affirming that a wholesale drug distributor does, in fact, have duties  
15 beyond reporting. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C.  
16 Cir. 2017). The D.C. Circuit Court upheld the revocation of Master  
17 Pharmaceutical’s license and determined that DEA regulations require that in  
18 addition to reporting suspicious orders, distributors must “decline to ship the  
19 order, or conduct some ‘due diligence’ and—if it is able to determine that the  
20 order is not likely to be diverted into illegal channels—ship the order.” *Id.* at 212.  
21 Master Pharmaceutical was in violation of legal requirements because it failed to  
22 conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226.  
23 A distributor’s investigation must dispel all the red flags giving rise to suspicious  
24 circumstances prior to shipping a suspicious order. *Id.* at 226. The Circuit Court  
25 also rejected the argument made by the HDMA and NACDS (quoted above), that,  
26 allegedly, the DEA had created or imposed new duties. *Id.* at 220.

27 236. Wholesale Distributor McKesson has recently been forced to  
28 specifically admit to breach of its duties to monitor, report, and prevent suspicious

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26 <sup>153</sup> *Id.* at \*24–25.

27 <sup>154</sup> *Id.* at \*26.

28 <sup>155</sup> See Brief of HDMA, 2012 WL 1637016, at \*3 (arguing the wholesale  
distributor industry “does not know the rules of the road because” they claim  
(inaccurately) that the “DEA has not adequately explained them”).

orders. Pursuant to an Administrative Memorandum of Agreement (“2017 Agreement”) entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”<sup>156</sup> Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a).”<sup>157</sup> McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers.”<sup>158</sup> Due to these violations, McKesson agreed that its authority to distribute controlled substances from numerous facilities would be partially suspended.<sup>159</sup>

237. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of

<sup>156</sup> See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

<sup>157</sup> *Id.* at 4.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* at 6.

1 controlled substances to the DEA.<sup>160</sup> In the 2008 Settlement Agreement,  
 2 McKesson “recognized that it had a duty to monitor its sales of all controlled  
 3 substances and report suspicious orders to DEA,” but had failed to do so.<sup>161</sup> The  
 4 2017 Memorandum of Agreement documents that McKesson continued to breach  
 5 its admitted duties by “fail[ing] to properly monitor its sales of controlled  
 6 substances and/or report suspicious orders to DEA, in accordance with  
 7 McKesson’s obligations.”<sup>162</sup> As a result of these violations, McKesson was fined  
 8 and required to pay to the United States \$150,000,000.<sup>163</sup>

9 238. Even though McKesson had been sanctioned in 2008 for failure to  
 10 comply with its legal obligations regarding controlling diversion and reporting  
 11 suspicious orders, and even though McKesson had specifically agreed in 2008 that  
 12 it would no longer violate those obligations, McKesson continued to violate the  
 13 laws in contrast to its written agreement not to do so.

14 239. Because of the Distributor Defendants’ refusal to abide by their legal  
 15 obligations, the DEA has repeatedly taken administrative action to attempt to  
 16 force compliance. For example, in May 2014, the United States Department of  
 17 Justice, Office of the Inspector General, Evaluation and Inspections Divisions,  
 18 reported that the DEA issued final decisions in 178 registrant actions between  
 19 2008 and 2012.<sup>164</sup> The Office of Administrative Law Judges issued a  
 20

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21 <sup>160</sup> *Id.* at 4.

22 <sup>161</sup> *Id.*

23 <sup>162</sup> *Id.*; *see also* Settlement Agreement and Release between the U.S. and  
 24 McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and  
 25 Release] (“McKesson acknowledges that, at various times during the Covered  
 26 Time Period [2009-2017], it did not identify or report to DEA certain orders placed  
 by certain pharmacies, which should have been detected by McKesson as  
 suspicious, in a manner fully consistent with the requirements set forth in the 2008  
 MOA.”), <https://www.justice.gov/opa/press-release/file/928471/download>.

27 <sup>163</sup> *See* 2017 Settlement Agreement and Release, at 6.

28 <sup>164</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of  
 Justice, *The Drug Enforcement Administration’s Adjudication of Registrant*  
*Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.<sup>165</sup> These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough,

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<sup>165</sup> *Id.*

Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);

- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

240. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.<sup>166</sup>

<sup>166</sup> See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9\\_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, [https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf\\_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.



241. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

242. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain, and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”<sup>167</sup> Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

243. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”<sup>168</sup> Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

244. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. The Plaintiffs did not know of the existence or scope of Defendants’

<sup>167</sup> Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0\\_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html).

<sup>168</sup> Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e\\_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html).



1 industry-wide fraud and could not have acquired such knowledge earlier through  
2 the exercise of reasonable diligence.

3 245. Meanwhile, the opioid epidemic rages unabated in the Nation, the  
4 State, and in Plaintiffs' Community.

5 246. The epidemic still rages because the fines and suspensions imposed  
6 by the DEA do not change the conduct of the industry. The distributors, including  
7 the Distributor Defendants, pay fines as a cost of doing business in an industry  
8 that generates billions of dollars in annual revenue. They hold multiple DEA  
9 registration numbers and when one facility is suspended, they simply ship from  
10 another facility.

11 247. The wrongful actions and omissions of the Distributor Defendants  
12 which have caused the diversion of opioids and which have been a substantial  
13 contributing factor to and/or proximate cause of the opioid crisis are alleged in  
14 greater detail in the racketeering allegations below.

15 248. The Distributor Defendants have abandoned their duties imposed  
16 under federal and state law, taken advantage of a lack of DEA law enforcement,  
17 and abused the privilege of distributing controlled substances in the State and  
18 Plaintiffs' Community.

19 **D. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE**  
20 **TO PREVENT DIVERSION AND MONITOR, REPORT, AND**  
21 **PREVENT SUSPICIOUS ORDERS.**

22 249. The same legal duties to prevent diversion, and to monitor, report,  
23 and prevent suspicious orders of prescription opioids that were incumbent upon  
24 the Distributor Defendants were also legally required of the Manufacturer  
25 Defendants under federal law.

26 250. Under federal law, the Manufacturing Defendants were required to  
27 comply with the same licensing requirements and with the same rules regarding  
28 prevention of diversion and reporting suspicious orders, as set out above.

1           251. Like the Distributor Defendants, the Manufacturer Defendants were  
2 required to register with the DEA to manufacture schedule II controlled  
3 substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of  
4 such registration is the:

5           maintenance of effective controls against diversion of particular  
6 controlled substances and any controlled substance in schedule I or II  
7 compounded therefrom into other than legitimate medical, scientific,  
8 research, or industrial channels, by limiting the importation and bulk  
9 manufacture of such controlled substances to a number of  
establishments which can produce an adequate and uninterrupted  
supply of these substances under adequately competitive conditions  
for legitimate medical, scientific, research, and industrial purposes . . .

10 21 U.S.C. § 823(a)(1) (emphasis added).

11           252. Additionally, as “registrants” under Section 823, the Manufacturer  
12 Defendants were also required to monitor, report, and prevent suspicious orders of  
13 controlled substances:

14           The registrant shall design and operate a system to disclose to the  
15 registrant suspicious orders of controlled substances. The registrant  
16 shall inform the Field Division Office of the Administration in his  
17 area of suspicious orders when discovered by the registrant.  
Suspicious orders include orders of unusual size, orders deviating  
substantially from a normal pattern, and orders of unusual frequency.

18 21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 (“Any term used in this part  
19 shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part  
20 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is  
21 registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823  
22 or 958).” Like the Distributor Defendants, the Manufacture Defendants breached  
these duties.

23           253. The Manufacturer Defendants had access to and possession of the  
24 information necessary to monitor, report, and prevent suspicious orders and to  
25 prevent diversion. The Manufacturer Defendants engaged in the practice of  
26 paying “chargebacks” to opioid distributors. A chargeback is a payment made by  
27 a manufacturer to a distributor after the distributor sells the manufacturer’s  
28 product at a price below a specified rate. After a distributor sells a manufacturer’s

1 product to a pharmacy, for example, the distributor requests a chargeback from the  
 2 manufacturer and, in exchange for the payment, the distributor identifies to the  
 3 manufacturer the product, volume and the pharmacy to which it sold the product.  
 4 Thus, the Manufacturer Defendants knew – just as the Distributor Defendants  
 5 knew – the volume, frequency, and pattern of opioid orders being placed and  
 6 filled. The Manufacturer Defendants built receipt of this information into the  
 7 payment structure for the opioids provided to the opioid distributors.

8 254. Federal statutes and regulations are clear: just like opioid  
 9 distributors, opioid manufacturers are required to “design and operate a system to  
 10 disclose . . . suspicious orders of controlled substances” and to maintain “effective  
 11 controls against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

12 255. The Department of Justice has recently confirmed the suspicious  
 13 order obligations clearly imposed by federal law upon opioid manufacturers,  
 14 fining Mallinckrodt \$35 million for failure to report suspicious orders of  
 15 controlled substances, including opioids, and for violating recordkeeping  
 16 requirements.<sup>169</sup>

17 256. In the press release accompanying the settlement, the Department of  
 18 Justice stated: Mallinckrodt “did not meet its obligations to detect and notify DEA  
 19 of suspicious orders of controlled substances such as oxycodone, the abuse of  
 20 which is part of the current opioid epidemic. These suspicious order monitoring  
 21 requirements exist to prevent excessive sales of controlled substances, like  
 22 oxycodone . . . . Mallinckrodt’s actions and omissions formed a link in the chain  
 23 of supply that resulted in millions of oxycodone pills being sold on the street. . . .  
 24  
 25

26 <sup>169</sup> See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record  
 27 \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical  
 28 Drugs and for Recordkeeping Violations (July 11, 2017),  
<https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

1 ‘Manufacturers and distributors have a crucial responsibility to ensure that  
2 controlled substances do not get into the wrong hands. . . .’<sup>170</sup>

3 257. Among the allegations resolved by the settlement, the government  
4 alleged “Mallinckrodt failed to design and implement an effective system to detect  
5 and report ‘suspicious orders’ for controlled substances – orders that are unusual  
6 in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied  
7 distributors, and the distributors then supplied various U.S. pharmacies and pain  
8 clinics, an increasingly excessive quantity of oxycodone pills without notifying  
9 DEA of these suspicious orders.”<sup>171</sup>

10 258. The Memorandum of Agreement entered into by Mallinckrodt  
11 (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt  
12 had a responsibility to maintain effective controls against diversion, including a  
13 requirement that it review and monitor these sales and report suspicious orders to  
14 DEA.”<sup>172</sup>

15 259. The 2017 Mallinckrodt MOA further details the DEA’s allegations  
16 regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid  
17 manufacturer:

18 With respect to its distribution of oxycodone and hydrocodone  
19 products, Mallinckrodt’s alleged failure to distribute these controlled  
20 substances in a manner authorized by its registration and  
21 Mallinckrodt’s alleged failure to operate an effective suspicious order  
22 monitoring system and to report suspicious orders to the DEA when  
23 discovered as required by and in violation of 21 C.F.R. § 1301.74(b).  
24 The above includes, but is not limited to Mallinckrodt’s alleged failure  
25 to:

- 26 i. conduct adequate due diligence of its customers;
- 27 ii. detect and report to the DEA orders of unusual size and  
28 frequency;

25 <sup>170</sup> *Id.* (quoting DEA Acting Administrator Chuck Rosenberg).

26 <sup>171</sup> *Id.*

27 <sup>172</sup> Administrative Memorandum of Agreement between the United States  
28 Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and  
its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (“2017 Mallinckrodt MOA”).

1                   iii. detect and report to the DEA orders deviating substantially  
 2                   from normal patterns including, but not limited to, those  
 3                   identified in letters from the DEA Deputy Assistant  
 4                   Administrator, Office of Diversion Control, to registrants dated  
 5                   September 27, 2006 and December 27, 2007:

- 6                   1. orders that resulted in a disproportionate amount of a  
 7                   substance which is most often abused going to a  
 8                   particular geographic region where there was known  
 9                   diversion,
- 10                  2. orders that purchased a disproportionate amount of a  
 11                  substance which is most often abused compared to other  
 12                  products, and
- 13                  3. orders from downstream customers to distributors who  
 14                  were purchasing from multiple different distributors, of  
 15                  which Mallinckrodt was aware;

16                  iv. use "chargeback" information from its distributors to evaluate  
 17                  suspicious orders. Chargebacks include downstream  
 18                  purchasing information tied to certain discounts, providing  
 19                  Mallinckrodt with data on buying patterns for Mallinckrodt  
 20                  products; and

21                  v. take sufficient action to prevent recurrence of diversion by  
 22                  downstream customers after receiving concrete information of  
 23                  diversion of Mallinckrodt product by those downstream  
 24                  customers.<sup>173</sup>

25                  260. Mallinckrodt agreed that its “system to monitor and detect suspicious  
 26                  orders did not meet the standards outlined in letters from the DEA Deputy  
 27                  Administrator, Office of Diversion Control, to registrants dated September 27,  
 28                  2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the  
 importance of the prevention of diversion of the controlled substances they  
 manufacture” and would “design and operate a system that meets the requirements  
 of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction  
 information to identify suspicious orders of any Mallinckrodt product. Further,  
 Mallinckrodt agrees to notify DEA of any diversion and/or suspicious

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<sup>173</sup> 2017 Mallinckrodt MOA at 2-3.

1 circumstances involving any Mallinckrodt controlled substances that Mallinckrodt  
2 discovers.”<sup>174</sup>

3 261. Mallinckrodt acknowledged that “[a]s part of their business model  
4 Mallinckrodt collects transaction information, referred to as chargeback data, from  
5 their direct customers (distributors). The transaction information contains data  
6 relating to the direct customer sales of controlled substances to ‘downstream’  
7 registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA  
8 when Mallinckrodt concludes that the chargeback data or other information  
9 indicates that a downstream registrant poses a risk of diversion.”<sup>175</sup>

10 262. The same duties imposed by federal law on Mallinckrodt were  
11 imposed upon all Manufacturer Defendants.

12 263. The same business practices utilized by Mallinckrodt regarding  
13 “charge backs” and receipt and review of data from opioid distributors regarding  
14 orders of opioids were utilized industry-wide among opioid manufacturers and  
15 distributors, including, upon information and belief, the other Manufacturer  
16 Defendants.

17 264. Through, *inter alia*, the charge back data, the Manufacturer  
18 Defendants could monitor suspicious orders of opioids.

19 265. The Manufacturer Defendants failed to monitor, report, and halt  
20 suspicious orders of opioids as required by federal and state law.

21 266. The Manufacturer Defendants’ failures to monitor, report, and halt  
22 suspicious orders of opioids were intentional and unlawful.

23 267. The Manufacturer Defendants have misrepresented their compliance  
24 with federal and state law.

25  
26  
27  
28 <sup>174</sup> *Id.* at 3-4.

<sup>175</sup> *Id.* at 5.



1           268. The Manufacturer Defendants enabled the supply of prescription  
2           opioids to obviously suspicious physicians and pharmacies, enabled the illegal  
3           diversion of opioids, aided criminal activity, and disseminated massive quantities  
4           of prescription opioids into the black market.

5           269. The wrongful actions and omissions of the Manufacturer Defendants  
6           which have caused the diversion of opioids and which have been a substantial  
7           contributing factor to and/or proximate cause of the opioid crisis are alleged in  
8           greater detail in the racketeering allegations below.

9           270. The Manufacturer Defendants' actions and omissions in failing to  
10          effectively prevent diversion and failing to monitor, report, and prevent suspicious  
11          orders have enabled the unlawful diversion of opioids into Plaintiffs' Community.

12           **E. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF**  
13           **LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND**  
14           **SUBSTANTIAL DAMAGES.**

15          271. As the Manufacturer Defendants' efforts to expand the market for  
16          opioids increased so have the rates of prescription and sale of their products —  
17          and the rates of opioid-related substance abuse, hospitalization, and death among  
18          the people of the State and the Plaintiffs' Community. The Distributor Defendants  
19          have continued to unlawfully ship these massive quantities of opioids into  
20          communities like the Plaintiffs' Community, fueling the epidemic.

21          272. There is a "parallel relationship between the availability of  
22          prescription opioid analgesics through legitimate pharmacy channels and the  
23          diversion and abuse of these drugs and associated adverse outcomes."<sup>176</sup>

24          273. Opioid analgesics are widely diverted and improperly used, and the  
25          widespread use of the drugs has resulted in a national epidemic of opioid overdose  
26          deaths and addictions.<sup>177</sup>

27  
28          <sup>176</sup> See Richard C. Dart et al., Trends in Opioid Analgesic Abuse and Mortality in  
the United States, 372 N. Eng. J. Med. 241 (2015).

1           274. The epidemic is “directly related to the increasingly widespread  
2 misuse of powerful opioid pain medications.”<sup>178</sup>

3           275. The increased abuse of prescription painkillers along with growing  
4 sales has contributed to a large number of overdoses and deaths.<sup>179</sup>

5           276. As shown above, the opioid epidemic has escalated in Plaintiffs’  
6 Community with devastating effects. Substantial opiate-related substance abuse,  
7 hospitalization and death mirrors Defendants’ increased distribution of opiates.

8           277. Because of the well-established relationship between the use of  
9 prescription opiates and the use of non-prescription opioids, like heroin, the  
10 massive distribution of opioids to Plaintiffs’ Community and areas from which  
11 such opioids are being diverted into Plaintiffs’ Community, has caused the  
12 Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

13           278. Prescription opioid abuse, addiction, morbidity, and mortality are  
14 hazards to public health and safety in the State and in Plaintiffs’ Community.

15           279. Heroin abuse, addiction, morbidity, and mortality are hazards to  
16 public health and safety in the State and in Plaintiffs’ Community.

17           280. Defendants repeatedly and purposefully breached their duties under  
18 state and federal law, and such breaches are direct and proximate causes of, and/or  
19 substantial factors leading to, the widespread diversion of prescription opioids for  
20 nonmedical purposes into the Plaintiffs’ Community.

21           281. The unlawful diversion of prescription opioids is a direct and  
22 proximate cause of, and/or substantial factor leading to, the opioid epidemic,  
23

24 <sup>177</sup> See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—*  
25 *Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

26 <sup>178</sup> See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*,  
374 N. Eng. J. Med. 1480 (2016).

27 <sup>179</sup> See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep’t of  
28 Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels  
(Nov. 1, 2011),  
[https://www.cdc.gov/media/releases/2011/p1101\\_flu\\_pain\\_killer\\_overdose.html](https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html).

1 prescription opioid abuse, addiction, morbidity and mortality in the State and  
 2 Plaintiffs' Community. This diversion and the epidemic are direct causes of  
 3 foreseeable harms incurred by the Plaintiffs and Plaintiffs' Community.

4 282. Defendants' intentional and/or unlawful conduct resulted in direct  
 5 and foreseeable, past and continuing, economic damages for which Plaintiffs seek  
 6 relief, as alleged herein. Plaintiffs also seek the means to abate the epidemic  
 7 created by Defendants' wrongful and/or unlawful conduct.

8 283. The County seeks economic damages from the Defendants as  
 9 reimbursement for the costs associated with damage to its property and past  
 10 efforts to eliminate the hazards to public health and safety.

11 284. Plaintiffs seek economic damages from the Defendants to pay for the  
 12 cost to permanently eliminate the hazards to public health and safety and abate the  
 13 temporary public nuisance.

14 285. To eliminate the hazard to public health and safety, and abate the  
 15 public nuisance, a "multifaceted, collaborative public health and law enforcement  
 16 approach is urgently needed."<sup>180</sup>

17 286. A comprehensive response to this crisis must focus on preventing  
 18 new cases of opioid addiction, identifying early opioid-addicted individuals, and  
 19 ensuring access to effective opioid addiction treatment while safely meeting the  
 20 needs of patients experiencing pain.<sup>181</sup>

21  
 22  
 23  
 24  
 25 <sup>180</sup> See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—*  
*United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016), at  
 1145.

26 <sup>181</sup> See Johns Hopkins Bloomberg School of Public Health, *The Prescription*  
 27 *Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds.,  
 2015), [http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-](http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf)  
 28 [and-effectiveness/research/prescription-](http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf)  
[opioids/JHSPH\\_OPIOID\\_EPIDEMIC\\_REPORT.pdf](http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf).

1           287. These community-based problems require community-based  
2 solutions that have been limited by “budgetary constraints at the state and Federal  
3 levels.”<sup>182</sup>

4           288. Having profited enormously through the aggressive sale, misleading  
5 promotion, and irresponsible distribution of opiates, Defendants should be  
6 required to take responsibility for the financial burdens their conduct has inflicted  
7 upon the Plaintiffs and Plaintiffs’ Community.

8           **F. DEFENDANTS’ FRAUDULENT AND DECEPTIVE MARKETING**  
9           **OF OPIOIDS DIRECTLY CAUSED HARM TO THE COUNTY.**

10          289. In the first instance, Plaintiff The County was damaged directly,  
11 through its payments of false claims for chronic opioid therapy by (a) its self-  
12 insured health care plans and (b) its workers’ compensation program.

13          290. The Defendants’ marketing of opioids caused health care providers to  
14 prescribe and Plaintiff, through its health plans and workers’ compensation  
15 program, to pay for prescriptions of opioids to treat chronic pain. Because of the  
16 Defendants’ unbranded marketing, health care providers wrote and the County  
17 paid for prescriptions opioids for chronic pain that were filled not only with their  
18 drugs, but with opioids sold by other manufacturers. All of these prescriptions  
19 were caused by Defendants’ fraudulent marketing and therefore all of them  
20 constitute false claims. Because, as laid out below, The County is obligated to  
21 cover medically necessary and reasonably required care, it had no choice but to  
22 pay these false and fraudulent claims.

23          291. The fact that the County would pay for these ineligible prescriptions  
24 is both the foreseeable and intended consequence of the Defendants’ fraudulent  
25 marketing scheme. The Defendants set out to change the medical and general  
26

27  
28 <sup>182</sup> See Office of Nat’l Drug Control Policy, Exec. Office of the President,  
*Epidemic: Responding to America’s Prescription Drug Abuse Crisis* (2011),  
[https://www.ncjrs.gov/pdffiles1/ondcp/rx\\_abuse\\_plan.pdf](https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf).

consensus supporting chronic opioid therapy *so that* doctors would prescribe and government payors, such as the County, would pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

### **1. Increase in Opioid Prescribing Nationally**

292. Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain worked. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide. During 2009, they provided 83 million more.

293. Opioid prescriptions increased even as the percentage of patients visiting the doctor for pain remained constant.

294. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.<sup>183</sup>

295. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, "[o]pioids are the most common means of treatment for chronic pain."<sup>184</sup> From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. This is the result not of an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010 – even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications decreased. For back

<sup>183</sup> Matthew Daubress et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51 (10) *Med. Care* 870 (2013).

<sup>184</sup> Deborah Grady et al., *Opioids for Chronic Pain*, 171 (16) *Arch. Intern. Med.* 1426 (2011).

1 pain alone – one of the most common chronic pain conditions – the percentage of  
 2 patients prescribed opioids increased from 19% to 29% between 1999 and 2010,  
 3 even as the use of NSAIDs, or acetaminophen declined and referrals to physical  
 4 therapy remained steady – and climbing.

5 296. This increase corresponds with, and was caused by, the Defendants’  
 6 massive marketing push. The industry’s spending nationwide on marketing of  
 7 opioids stood at more than \$20 million per quarter and \$91 million annually in  
 8 2000. By 2011, that figure hit its peak of more than \$70 million per quarter and  
 9 \$288 million annually, a more than three-fold increase. By 2014, the figures  
 10 dropped to roughly \$45 million per quarter and \$182 million annually, as the  
 11 Defendants confronted increased concern regarding opioid addiction, abuse, and  
 12 diversion. Even so, the Defendants still spend double what they spent in 2000 on  
 13 opioid marketing.

14 297. By far the largest component of this spending was opioid drug  
 15 makers’ detailing visits to individual doctors, with total detailing expenditures  
 16 more than doubling between 2000 and 2014 and now standing at \$168 million  
 17 annually.

## 18 **2. The County’s Increased Spending on Opioids through Self-Insured** 19 **Health Care Plans and Workers’ Compensation Program.**

20 298. Commensurate with the Defendants’ heavy promotion of opioids and  
 21 the resultant massive upswing in prescribing of opioids nationally, the County has  
 22 seen its own spending on opioids – through claims paid by its health care plans  
 23 and workers’ compensation program – increase.

### 24 **i. Health Care Plans**

25 299. The County provides comprehensive health care benefits, including  
 26 prescription drugs coverage, to its employees. These benefits are provided under  
 27 one health plan that The County self-insures, including a preferred provider  
 28 organization (“PPO”) for employees.



1           300. The prescription drug plan under the PPO is self-insured: the costs of  
2 prescription drugs are paid directly by The County.

3           301. Throughout the relevant time period for this action, the PPO's  
4 prescription drug costs have been paid by The County.

5           302. Doctors submit claims directly to The County's applicable health  
6 plan for their costs associated with prescribing opioids, including office visits and  
7 toxicology screens for patients prescribed opioids. In addition, prescriptions for  
8 opioids written by these doctors for patients covered by The County's self-insured  
9 health plans are filled by pharmacies, which submit claims for reimbursement to  
10 The County's pharmacy benefit manager.

11           303. The County's applicable health plans provide benefits for all  
12 "medically necessary" services associated with opioids, including treatment  
13 related to any adverse outcomes from chronic opioid therapy, such as overdose or  
14 addiction treatment.

15           304. The Defendants caused doctors and pharmacies to submit, and The  
16 County to pay, claims to its health plans that were false by: (a) causing doctors to  
17 write prescriptions for chronic opioid therapy based on deceptive representations  
18 regarding the risks, benefits, and superiority of those drugs; (b) causing doctors to  
19 certify that these prescriptions and associated services were medically necessary;  
20 (c) causing claims to be submitted for drugs that were promoted for off-label uses  
21 and misbranded, and therefore not FDA-approved; and (d) distorting the standard  
22 of care for treatment of chronic pain so that doctors would feel not only that it  
23 was appropriate, but required, that they prescribe and continue prescriptions for  
24 opioids long-term to treat chronic pain. Each – or any – of these factors made  
25 claims to The County for chronic opioid therapy false.

26           305. The County's self-insured health plans only cover the cost of  
27 prescription drugs that are medically necessary and dispensed for a FDA-approved  
28 purpose. Prescriptions drugs that are not medically necessary or that are dispensed

1 for a non-FDA approved purpose are expressly excluded from coverage under The  
2 County's plans. Generally, under any PPO plan, a medically necessary  
3 prescription is one which is "customary for the treatment or diagnosis of an illness  
4 or injury, and is consistent with generally accepted medical standards."

5 306. Doctors who care for The County employees and their covered  
6 dependents are bound by the provider agreements that entitle them to participate  
7 in The County's health plans. These agreements generally permit doctors to  
8 charge only for treatments that are medically necessary.

9 307. The County is obligated to pay for the medically necessary treatment  
10 of covered employees.

11 308. In prescribing opioids for chronic pain, doctors certify that the  
12 treatment is medically necessary and the drugs dispense for an FDA approved  
13 purpose, and – at least with respect to the self-insured plans (the PPO) – the health  
14 plans authorize payment from The County's funds.

15 309. As described above, the use of opioids to treat chronic pain is not "in  
16 accordance with generally accepted standards of medical practice" nor "clinically  
17 appropriate . . . and considered effective for the patient's illness, injury or  
18 disease."

19 310. Further, the Defendants' deceptive marketing rendered opioids  
20 misbranded as prescribed for chronic pain because they were false and misleading  
21 and because, by minimizing the risks associated with the drugs, they did not  
22 contain adequate directions for use. The written, printed, or graphic matter  
23 accompanying the Defendants' drugs did not accurately describe the risks  
24 associated with long-term use of their products, rendering them misbranded. Due  
25 to this misbranding, the Defendants' opioids were not FDA-approved, within the  
26 meaning of The County's health plans, for the long-term treatment of chronic  
27 pain.  
28

1           311. For each and all of the reasons above, chronic opioid therapy and its  
2 attendant and consequential costs are not eligible for reimbursement through The  
3 County's health plan. The County would not have knowingly reimbursed claims  
4 for prescription drugs that were not eligible for coverage.

5           312. As a result of the Defendants' deceptive marketing, The County's  
6 patients who used opioids long-term to treat chronic pain also incurred additional  
7 costs and suffered additional injuries requiring care, including doctors' visits,  
8 toxicology screens, hospitalization for overdoses, treatment and other adverse  
9 effects of opioids, and long-term disability, among others, which caused The  
10 County to incur additional costs.

11           313. The costs incurred by The County include, but are not limited to,  
12 doctor visits, which would also be included with these prescriptions. This includes  
13 prescriptions that also were caused by Defendants' deceptive marketing, including  
14 prescriptions for Defendants' generic opioid products and prescriptions for  
15 opioids from other manufacturers. These figures do not reflect the cost to The  
16 County of prescribing opioids, such as doctors' visits or toxicology screens, or the  
17 costs of treating the adverse effects of prescribing opioids long-term, such as  
18 overdose and addiction. They also do not reflect the total damages for all years to  
19 The County, which will be determined at trial, and which will include costs to the  
20 health plan for the treatment of opioid abuse and dependency.

21           314. The claims – and the attendant and consequential costs – for opioids  
22 prescribed for chronic pain, as opposed to acute and cancer or end-of-life pain,  
23 were ineligible for payment and the result of the Defendants' deceptive and unfair  
24 conduct.

25           **ii. Workers' Compensation Programs**

26           315. Plaintiff The County, through a fully self-insured program, provides  
27 workers' compensation, including prescription drug benefits, to eligible  
28 employees injured in the course of their employment. When an employee is

1 injured on the job, he or she may file a claim for workers' compensation, and if  
2 the injury is deemed work-related, The County is responsible for paying its share  
3 of the employee's medical costs and lost wages.

4 316. The County uses a third party vendor to help manage medical  
5 benefits under the workers' compensation program. Doctors submit claims to the  
6 County's workers' compensation program for the costs associated with  
7 prescribing opioids, including office visits and toxicology screens for patients  
8 prescribed opioids.

9 317. Upon information and belief, the County's vendor uses a pharmacy  
10 and drug utilization management program to manage prescriptions for the  
11 County's workers' compensation program.

12 318. The County's workers' compensation program covers all costs  
13 associated with opioids, including treatment related to any adverse outcomes from  
14 chronic opioid therapy, such as addiction treatment.

15 319. The Defendants cause doctors and pharmacies to submit, and the  
16 County to pay claims to its workers' compensation program that were false by: (a)  
17 causing doctors to write prescriptions for chronic opioid therapy based on  
18 deceptive representations regarding the risks, benefits, and superiority of those  
19 drugs; (b) causing doctors to certify that these prescriptions and associated  
20 services were medically necessary; (c) causing claims to be submitted for drugs  
21 that were promoted for off-label uses and misbranded, and therefore not FDA-  
22 approved; and (d) distorting the standard of care for treatment of chronic pain so  
23 that doctors would feel not only that it was appropriate, but required, that they  
24 prescribe and continue prescriptions for opioids long-term to treat chronic pain.  
25 Each – or any – of these factors made claims to the County for chronic opioid  
26 therapy false.

27 320. The California Workers' Compensation law requires employers or  
28 their insurers to pay for, *inter alia*, medical and surgical services, hospital and

1 nursing services, and medicines that are reasonably required to cure or relieve the  
2 injured worker from the effects of his or her injury. Cal. Lab. Code § 4600.

3 321. In prescribing opioids for chronic pain, doctors certify that the  
4 treatment is medically necessary and reasonably required, and the workers'  
5 compensation program authorizes payment from The County's funds.

6 322. The County's workers' compensation program is obligated to cover  
7 all "medically necessary" and "reasonably required" treatment arising from a  
8 compensable work-related injury.

9 323. As described above, however, the use of opioids to treat chronic pain  
10 is not medically necessary or reasonably required in that their risks do not  
11 materially exceed their benefits; they do not improve physiological function; and  
12 their use is not consistent with guidelines that are *scientifically based* (as opposed  
13 to marketing driven).

14 324. Nevertheless, the amount of such prescriptions paid by worker's  
15 compensation programs is monumental. A study of the National Council on  
16 Compensation Insurance ("NCCI") concluded that, in 2011, approximately 38%  
17 of pharmacy costs in workers' compensation are for opioids and opioid  
18 combinations, amounting to approximately \$1.4 billion.

19 325. Upon information and belief, those trends are reflected in the  
20 County's experience with paying for opioids through its worker's compensation  
21 plan.

22 326. The County incurred costs associated with the prescribing of opioids,  
23 such as doctors' visits or toxicology screens, and the costs of treating the adverse  
24 effects of prescribing opioids long-term such as overdose and addiction.

25 327. However, the costs of long-term opioid use are not limited to costs of  
26 opioid prescriptions. Long-term opioid use is accompanied by a host of  
27 consequential costs, including costs related to abuse, addiction, and death.  
28

1           328. These claims – and their attendant and consequential costs – for  
2           opioids prescribed for chronic pain, as opposed to acute and cancer or end-of-life  
3           pain, were ineligible for payment and the result of the Defendant’s fraudulent  
4           scheme.

5  
6           **iii. The County’s Increased Costs Correlate with the Defendants’  
Promotion.**

7           329. Upon information and belief, a review of the County’s costs related  
8           to opioid prescriptions, and the costs associated with those prescriptions, will  
9           show that as the Defendants spent more to promote their drugs, doctors began  
10          prescribing them more often and as a result, the costs to the County went up.

11          330. It is also distressing (and a sign of further problems ahead) that the  
12          drop in opioid prescribing beginning in 2014 has been accompanied by a  
13          corresponding increase in the Defendants’ promotional spending, which is headed  
14          towards a new high, despite evidence of the grave toll that opioids are taking on  
15          law enforcement, public health, and individual lives.

16          331. The County asserts that each Defendant made misrepresentations or  
17          misrepresentation by omission of material facts by their employees, agents, or co-  
18          conspirators to prescribing physicians who then wrote opioid prescriptions for  
19          which the County paid. Furthermore, the County asserts that specific details about  
20          the names of the employees, agents, or co-conspirators, the substance of the  
21          misrepresentations or omissions, the time and date and location of said  
22          misrepresentations or omissions, and the names of the prescribing physicians who  
23          were exposed to each Defendants’ misrepresentations or omissions were closely  
24          tracked by the Defendants, are in the exclusive possession of the Defendants and  
25          the County reasonably believes that such information will be disclosed in  
26          discovery.



**G. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS  
ARE ESTOPPED FROM ASSERTING STATUTES OF  
LIMITATIONS AS DEFENSES.**

**1. Enforcement of a Public Right.**

332. No statute of limitation can be pleaded against the Plaintiffs, which seek to enforce strictly public rights.

**2. Continuing Conduct.**

333. Plaintiffs contend they continue to suffer harm from the unlawful actions by the Defendants.

334. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

**3. Equitable Estoppel.**

335. To the extent any statute of limitations defense would apply, Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiffs and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiffs, and Plaintiffs' Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiffs, and Plaintiffs' Community, that they are working to curb the opioid epidemic.

1           336. For example, a Cardinal Health executive claimed that it uses  
 2 “advanced analytics” to monitor its supply chain, and assured the public it was  
 3 being “as effective and efficient as possible in constantly monitoring, identifying,  
 4 and eliminating any outside criminal activity.”<sup>185</sup>

5           337. Similarly, McKesson publicly stated that it has a “best-in-class  
 6 controlled substance monitoring program to help identify suspicious orders,” and  
 7 claimed it is “deeply passionate about curbing the opioid epidemic in our  
 8 country.”<sup>186</sup>

9           338. Moreover, in furtherance of their effort to affirmatively conceal their  
 10 conduct and avoid detection, the Distributor Defendants, through their trade  
 11 associations, HDMA and NACDS, filed an *amicus* brief in *Masters*  
 12 *Pharmaceuticals*, which made the following statements:<sup>187</sup>

- 13           a. “HDMA and NACDS members not only have statutory and  
 14 regulatory responsibilities to guard against diversion of controlled  
 15 prescription drugs, but undertake such efforts as responsible  
 members of society.”
- 16           b. “DEA regulations that have been in place for more than 40 years  
 17 require distributors to *report* suspicious orders of controlled  
 substances to DEA based on information readily available to them  
 (e.g., a pharmacy’s placement of unusually frequent or large orders).”
- 18           c. “Distributors take seriously their duty to report suspicious orders,  
 19 utilizing both computer algorithms and human review to detect  
 suspicious orders based on the generalized information that *is*  
 20 available to them in the ordering process.”
- 21           d. “A particular order or series of orders can raise red flags because of  
 22 its unusual size, frequency, or departure from typical patterns with a  
 23 given pharmacy.”

24  
 25 <sup>185</sup> Bernstein et al., *supra*.

26 <sup>186</sup> Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as*  
 27 *the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016,  
 28 [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e\\_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html).

<sup>187</sup> Brief for HDMA and NACDS, 2016 WL 1321983, at \*3-4, \*25.

- 1 e. “Distributors also monitor for and report abnormal behavior by  
2 pharmacies placing orders, such as refusing to provide business  
3 contact information or insisting on paying in cash.”

4 Through the above statements made on their behalf by their trade associations,  
5 and other similar statements assuring their continued compliance with their legal  
6 obligations, the Distributor Defendants not only acknowledged that they  
7 understood their obligations under the law, but they further affirmed that their  
8 conduct was in compliance with those obligations.

9 339. The Distributor Defendants have also concealed and prevented  
10 discovery of information, including data from the ARCOS database that will  
11 confirm their identities and the extent of their wrongful and illegal activities.

12 340. The Manufacturer Defendants distorted the meaning or import of  
13 studies they cited and offered them as evidence for propositions the studies did not  
14 support. The Manufacturer Defendants invented “pseudoaddiction” and promoted  
15 it to an unsuspecting medical community. The Manufacturer Defendants provided  
16 the medical community with false and misleading information about ineffectual  
17 strategies to avoid or control opioid addiction. The Manufacturer Defendants  
18 recommended to the medical community that dosages be increased, without  
19 disclosing the risks. The Manufacturer Defendants spent millions of dollars over a  
20 period of years on a misinformation campaign aimed at highlighting opioids’  
21 alleged benefits, disguising the risks, and promoting sales. The medical  
22 community, consumers, the State, and Plaintiffs’ Community were duped by the  
23 Manufacturer Defendants’ campaign to misrepresent and conceal the truth about  
24 the opioid drugs that they were aggressively pushing in the State and in Plaintiffs’  
25 Community.

26 341. Defendants intended that their actions and omissions would be relied  
27 upon, including by Plaintiffs and Plaintiffs’ Community. Plaintiffs and Plaintiffs’  
28 Community did not know, and did not have the means to know, the truth due to  
Defendants’ actions and omissions.

1           342. The Plaintiffs and Plaintiffs' Community reasonably relied on  
2 Defendants' affirmative statements regarding their purported compliance with  
3 their obligations under the law and consent orders. To the extent statutes of  
4 limitations could apply to Plaintiffs' claims, Plaintiffs failed to commence an  
5 action within the statutory periods because of reliance on Defendants' wrongful  
6 conduct.

7           343. Defendants are estopped from asserting a statute of limitations  
8 defense because their conduct and misrepresentations were so unfair and  
9 misleading as to outweigh the public's interest in setting limitations on bringing  
10 actions.

#### 11           **4. Fraudulent Concealment**

12           344. To the extent any statute of limitations defense would apply,  
13 Plaintiffs' claims are further subject to equitable tolling, stemming from  
14 Defendants' knowing and fraudulent concealment of the facts alleged herein. As  
15 alleged herein, Defendants knew of the wrongful acts set forth above, had material  
16 information pertinent to their discovery, and concealed them from the Plaintiffs  
17 and Plaintiffs' Community. The Plaintiffs did not know, or could not have known  
18 through the exercise of reasonable diligence, of their causes of action, as a result  
19 of Defendants' conduct.

20           345. The purposes of the statutes of limitations period, if any, are satisfied  
21 because Defendants cannot claim prejudice due to a late filing where the Plaintiffs  
22 filed suit promptly upon discovering the facts essential to their claims, described  
23 herein, which Defendants knowingly concealed.

24           346. In light of their statements to the media, in legal filings and in  
25 settlements, it is clear that Defendants had actual or constructive knowledge that  
26 their conduct was deceptive, in that they consciously concealed the schemes set  
27 forth herein.

1           347. Defendants continually and secretly engaged in their scheme to avoid  
 2 compliance with their legal obligations. Only Defendants and their agents knew or  
 3 could have known about Defendants' unlawful actions because Defendants made  
 4 deliberate efforts to conceal their conduct. As a result of the above, the Plaintiffs  
 5 were unable to obtain vital information bearing on their claims absent any fault or  
 6 lack of diligence on their part.

7                                   **V. LEGAL CAUSES OF ACTION**

8   **COUNT I**

9   **PUBLIC NUISANCE**

10   **(Brought by The People Against all Defendants)**

11           348. Plaintiff, The People, incorporate by reference all other paragraphs of  
 12 this Complaint as if fully set forth here, and further allege as follows.

13           349. Each Defendant is liable for public nuisance because its conduct at  
 14 issue has caused an unreasonable and substantial interference with a right  
 15 common to the general public. *See Cty. of Santa Clara v. Atl. Richfield Co.*, 137  
 16 Cal. App. 4th 292, 305, 40 Cal. Rptr. 3d 313, 325 (2006) (cit. om.). The  
 17 interference is substantial "if it causes significant harm and unreasonable if its  
 18 social utility is outweighed by the gravity of the harm inflicted." *Id.* The causation  
 19 element of a public nuisance cause of action is satisfied if the defendant's conduct  
 20 is a substantial factor in bringing about the result. *People v. Conagra Grocery*  
 21 *Prod. Co.*, 17 Cal. App. 5th 51, 101-02, 227 Cal. Rptr. 3d 499, 543 (Ct. App.  
 22 2017), *reh'g denied* (Dec. 6, 2017), *review denied* (Feb. 14, 2018).

23           350. Under California law, a nuisance is "anything which is injurious to  
 24 health, including but not limited to the illegal sale of controlled substances, or is  
 25 indecent or offensive to the senses, or an obstruction to the free use of property, so  
 26 as to interfere with the comfortable enjoyment of life or property." Cal. Civ. Code  
 27 § 3479.  
 28

1           351. California defines a “public nuisance” as “one which affects at the  
2 same time an entire community or neighborhood, or any considerable number of  
3 persons, although the extent of the annoyance or damage inflicted upon  
4 individuals may be unequal.” Cal. Civ. Code § 3480.

5           352. Defendants have created a public nuisance under California law.

6           353. The People have standing to bring this claim to abate the public  
7 nuisance due to the opioid epidemic which was created by Defendants and which  
8 is affecting and causing harm in Plaintiffs’ Community. *See* Cal. Civ. Proc. Code  
9 § 731.

10          354. By causing dangerously addictive drugs to flood the community, and  
11 to be diverted for illicit purposes, in contravention of federal and state law, each  
12 Defendant has injuriously affected rights common to the general public,  
13 specifically including the rights of the people of the Plaintiffs’ Community to  
14 public health, public safety, public peace, public comfort, and public convenience.  
15 The public nuisance caused by Defendants’ diversion of dangerous drugs has  
16 caused substantial annoyance, inconvenience, and injury to the public.

17          355. By selling dangerously addictive opioid drugs diverted from a  
18 legitimate medical, scientific, or industrial purpose, Defendants have committed a  
19 course of conduct that injuriously affects the safety, health, and morals of the  
20 people of the Plaintiffs’ Community.

21          356. By failing to maintain a closed system that guards against diversion  
22 of dangerously addictive drugs for illicit purposes, Defendants injuriously affected  
23 public rights, including the right to public health, public safety, public peace, and  
24 public comfort of the people of the Plaintiffs’ Community.

25          357. By affirmatively promoting opioids for use for chronic pain,  
26 affirmatively promoting opioids as not addictive, affirmatively fostering a  
27 misunderstanding of the signs of addiction and how to reliably identify and safely  
28 prescribe opioids to patients predisposed to addiction, affirmatively exaggerating



1 the risks of competing medications like NSAIDs, affirmatively promoting their  
2 so-called abuse-deterrent opioid formulations and affirmatively identifying and  
3 targeting susceptible prescribers and vulnerable patient populations, Defendants  
4 injuriously affected public rights, including the right to public health, public  
5 safety, public peace, and public comfort of the people of the Plaintiffs'  
6 Community. The public nuisance caused by Defendants' affirmative promotion  
7 of opioids has caused substantial annoyance, inconvenience, and injury to the  
8 public.

9 358. Defendants' interference with the comfortable enjoyment of life in  
10 the Plaintiffs' Community is unreasonable because there is little social utility to  
11 opioid diversion and abuse, and any potential value is outweighed by the gravity  
12 of the harm inflicted by Defendants' actions.

13 359. The People allege that Defendants' wrongful and illegal actions have  
14 created a public nuisance. Each Defendant is liable for public nuisance because its  
15 conduct at issue has caused an unreasonable and substantial interference with a  
16 right common to the general public.

17 360. The Defendants have intentionally and/or unlawfully created a  
18 nuisance.

19 361. The residents of Plaintiffs' Community have a common right to be  
20 free from conduct that creates an unreasonable jeopardy to the public health,  
21 welfare and safety, and to be free from conduct that creates a disturbance and  
22 reasonable apprehension of danger to person and property.

23 362. Defendants intentionally, unlawfully, and recklessly manufacture,  
24 market, distribute, promote and sell prescription opioids that Defendants know, or  
25 reasonably should know, will be diverted, causing widespread distribution of  
26 prescription opioids in and/or to Plaintiffs' Community, resulting in addiction and  
27 abuse, an elevated level of crime, death and injuries to the residents of Plaintiffs'  
28

1 Community, a higher level of fear, discomfort and inconvenience to the residents  
2 of Plaintiffs' Community, and direct costs to Plaintiffs' Community.

3 363. Defendants have unlawfully and/or intentionally caused and  
4 permitted dangerous drugs under their control to be diverted such as to injure the  
5 Plaintiffs' Community and its residents.

6 364. Defendants have unlawfully and/or intentionally promoted and  
7 distributed opioids or caused opioids to be distributed without maintaining  
8 effective controls against diversion. Such conduct was illegal. Defendants'  
9 failures to maintain effective controls against diversion include Defendants'  
10 failure to effectively monitor for suspicious orders, report suspicious orders,  
11 and/or stop shipment of suspicious orders.

12 365. Defendants have caused a significant and unreasonable interference  
13 with the public health, safety, welfare, peace, comfort and convenience, and  
14 ability to be free from disturbance and reasonable apprehension of danger to  
15 person or property.

16 366. Defendants' conduct in illegally distributing and selling prescription  
17 opioids, or causing such opioids to be distributed and sold, where Defendants  
18 know, or reasonably should know, such opioids will be diverted and possessed  
19 and/or used illegally in Plaintiffs' Community is of a continuing nature.

20 367. Defendants' actions have been of a continuing nature and have  
21 produced a significant effect upon the public's rights, including the public's right  
22 to health and safety.

23 368. A violation of any rule or law controlling the distribution of a drug of  
24 abuse in Plaintiffs' Community and the State is a public nuisance.

25 369. Defendants' distribution of opioids while failing to maintain effective  
26 controls against diversion was proscribed by statute and regulation.

27 370. Defendants' ongoing conduct produces an ongoing nuisance, as the  
28 prescription opioids that they allow and/or cause to be illegally distributed and

1 possessed in Plaintiffs' Community will be diverted, leading to abuse, addiction,  
2 crime, and public health costs.

3 371. Because of the continued use and addiction caused by these illegally  
4 distributed opioids, The People will continue to fear for their health, safety and  
5 welfare, and will be subjected to conduct that creates a disturbance and reasonable  
6 apprehension of danger to person and property.

7 372. Defendants know, or reasonably should know, that their conduct will  
8 have an ongoing detrimental effect upon the public health, safety and welfare, and  
9 the public's ability to be free from disturbance and reasonable apprehension of  
10 danger to person and property.

11 373. Defendants know, or reasonably should know, that their conduct  
12 causes an unreasonable and substantial invasion of the public right to health,  
13 safety and welfare and the public's ability to be free from disturbance and  
14 reasonable apprehension of danger to person and property.

15 374. Defendants are aware, and at a bare minimum certainly should be  
16 aware, of the unreasonable interference that their conduct has caused in Plaintiffs'  
17 Community. Defendants are in the business of manufacturing, marketing, selling,  
18 and distributing prescription drugs, including opioids, which are specifically  
19 known to Defendants to be dangerous because *inter alia* these drugs are defined  
20 under federal and state law as substances posing a high potential for abuse and  
21 severe addiction. *See, e.g.*, 21 U.S.C. § 812 (b)(2). Defendants created an  
22 intentional nuisance. Defendants' actions created and expanded the abuse of  
23 opioids, drugs specifically codified as constituting severely harmful substances.

24 375. Defendants' conduct in promoting, marketing, distributing, and  
25 selling prescription opioids which the Defendants know, or reasonably should  
26 know, will likely be diverted for non-legitimate, non-medical use, creates a strong  
27 likelihood that these illegal distributions of opioids will cause death and injuries to  
28 residents in Plaintiffs' Community and otherwise significantly and unreasonably

1 interfere with public health, safety and welfare, and with The People's right to be  
2 free from disturbance and reasonable apprehension of danger to person and  
3 property.

4 376. It is, or should be, reasonably foreseeable to defendants that their  
5 conduct will cause deaths and injuries to residents in Plaintiffs' Community, and  
6 will otherwise significantly and unreasonably interfere with public health, safety  
7 and welfare, and with the public's right to be free from disturbance and reasonable  
8 apprehension of danger to person and property.

9 377. The prevalence and availability of diverted prescription opioids in the  
10 hands of irresponsible persons and persons with criminal purposes in Plaintiffs'  
11 Community not only causes deaths and injuries, but also creates a palpable  
12 climate of fear among residents in Plaintiffs' Community where opioid diversion,  
13 abuse, addiction are prevalent and where diverted opioids tend to be used  
14 frequently.

15 378. Defendants' conduct makes it easier for persons to divert prescription  
16 opioids, constituting a dangerous threat to the public.

17 379. Defendants' actions were, at the least, a substantial factor in opioids  
18 becoming widely available and widely used for non-medical purposes. Because of  
19 Defendants' affirmative promotion of opioids and special positions within the  
20 closed system of opioid distribution, without Defendants' actions, opioid use  
21 would not have become so widespread, and the enormous public health hazard of  
22 prescription opioid and heroin overuse, abuse, and addiction that now exists  
23 would have been averted.

24 380. The presence of diverted prescription opioids in Plaintiffs'  
25 Community, and the consequence of prescription opioids having been diverted in  
26 Plaintiffs' Community, proximately results in and/or substantially contributes to  
27 the creation of significant future costs to The People and to Plaintiffs' Community  
28

1 in order to enforce the law, equip its police force and treat the victims of opioid  
2 abuse and addiction.

3 381. Stemming the flow of illegally distributed prescription opioids, and  
4 abating the nuisance caused by the illegal flow of opioids, will help to alleviate  
5 this problem, save lives, prevent injuries and make Plaintiffs' Community a safer  
6 place to live.

7 382. Defendants' conduct is a direct and proximate cause of and/or a  
8 substantial contributing factor to opioid addiction and abuse in Plaintiffs'  
9 Community, costs that will be borne by Plaintiffs' Community and The People,  
10 and a significant and unreasonable interference with public health, safety and  
11 welfare, and with the public's right to be free from disturbance and reasonable  
12 apprehension of danger to person and property.

13 383. Defendants' conduct constitutes a public nuisance and, if unabated,  
14 will continue to threaten the health, safety and welfare of the residents of  
15 Plaintiffs' Community, creating an atmosphere of fear and addiction that tears at  
16 the residents' sense of well-being and security. The People have a clearly  
17 ascertainable right to prospectively abate conduct that perpetuates this nuisance.

18 384. Defendants created an intentional nuisance. Defendants' actions  
19 created and expanded the abuse of opioids, which are dangerously addictive, and  
20 the ensuing associated plague of prescription opioid and heroin addiction.  
21 Defendants knew the dangers to public health and safety that diversion of opioids  
22 would create in Plaintiffs' Community; however, Defendants intentionally and/or  
23 unlawfully failed to maintain effective controls against diversion through proper  
24 monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants  
25 intentionally and/or unlawfully distributed opioids or caused opioids to be  
26 distributed without reporting or refusing to fill suspicious orders or taking other  
27 measures to maintain effective controls against diversion. Defendants  
28 intentionally and/or unlawfully continued to ship and failed to halt suspicious

1 orders of opioids, or caused such orders to be shipped. Defendants intentionally  
2 and/or unlawfully promoted and marketed opioids in manners they knew to be  
3 false and misleading. Such actions were inherently dangerous.

4 385. Defendants knew the prescription opioids have a high likelihood of  
5 being diverted. It was foreseeable to Defendants that where Defendants distributed  
6 prescription opioids or caused such opioids to be distributed without maintaining  
7 effective controls against diversion, including monitoring, reporting, and refusing  
8 shipment of suspicious orders, that the opioids would be diverted, and create an  
9 opioid abuse nuisance in Plaintiffs' Community.

10 386. Defendants' actions also created a nuisance by acting recklessly,  
11 negligently and/or carelessly, in breach of their duties to maintain effective  
12 controls against diversion, thereby creating an unreasonable and substantial risk of  
13 harm.

14 387. Defendants acted with actual malice because Defendants acted with a  
15 conscious disregard for the rights and safety of other persons, and said actions  
16 have a great probability of causing substantial harm.

17 388. The public nuisance created, perpetuated and maintained by  
18 Defendants can be prospectively abated and further reoccurrence of such harm  
19 and inconvenience can be prevented.

20 389. The People further seek to prospectively abate the nuisance created  
21 by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing,  
22 substantial and persistent actions and omissions and interference with a right  
23 common to the public.

24 390. Defendants' intentional and unlawful actions and omissions and  
25 unreasonable interference with a right common to the public are of a continuing  
26 nature.

27 391. The public nuisance created by Defendants' actions is substantial and  
28 unreasonable – it has caused and continues to cause significant harm to the



community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to the following:

- a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
- b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. Even those residents of Plaintiffs' Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured and will endure both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- d. The opioid epidemic has increased and will increase health care costs.
- e. Employers have lost and will continue to lose the value of productive and healthy employees.
- f. Defendants' conduct created and continues to create an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.
- g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many are turning to heroin as a foreseeable result.
- h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids has increased and continues to increase the demands on health care services and law enforcement.
- i. The significant and unreasonable interference with the public rights caused by Defendants' conduct has taxed and continues to tax the human, medical, public health, law enforcement, and financial resources of the Plaintiffs' Community.

392. The People seek all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief and expenses to prospectively abate the nuisance.

393. Pursuant to California Code of Civil Procedure section 731, The People request an order from the Court on behalf of The People providing for abatement of Defendants' ongoing violations of California Civil Code Sections 3479 and 3480, and enjoining Defendants from future violations of California Civil Code Sections 3479 and 3480.

394. Each Defendant created or assisted in the creation of the epidemic of opioid use and injury and each Defendant is jointly and severally liable for abating it.

## COUNT II

## PUBLIC NUISANCE

**(Brought by The County Against all Defendants)**

395. Plaintiff, The County, incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

396. As set forth above, each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public. *See, e.g., Cty. of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 305, 40 Cal. Rptr. 3d 313, 325 (2006); Cal. Civ. Code §§ 3479; 3480.

397. Defendants have created a public nuisance under California law.

398. The County has standing to bring this claim for damages incurred to its property by the public nuisance due to the opioid epidemic which was created by Defendants and which is affecting and causing harm to The County. An action can be “brought by any person whose property is injuriously affected, or whose personal enjoyment is lessened by a nuisance, as defined in Section 3479 of the Civil Code, and by the judgment in that action the nuisance may be enjoined or

1 abated as well as damages recovered therefor.” Cal. Civ. Proc. Code § 731.  
 2 “Where a public entity can show it has a property interest injuriously affected by  
 3 the nuisance, then, like any other such property holder, it should be able to pursue  
 4 the full panoply of tort remedies available to private persons.” *Selma Pressure*  
 5 *Treating Co. v. Osmose Wood Preserving Co.*, 221 Cal. App. 3d 1601, 1616, 271  
 6 Cal. Rptr. 596, 604 (Ct. App. 1990).

7 399. The County has suffered harm to its property interests that is  
 8 different from the type of harm suffered by the general public and has incurred  
 9 substantial costs deriving from having to replace and retrofit its property that has  
 10 been damaged and is being damaged by Defendants’ intentional, unlawful, and  
 11 reckless manufacturing, marketing, distribution, promotion and sale of  
 12 prescription opioids.

13 400. Defendants intentionally, unlawfully, and recklessly manufacture,  
 14 market, distribute, promote and sell prescription opioids that Defendants know, or  
 15 reasonably should know, will be diverted, causing widespread distribution of  
 16 prescription opioids in and/or to Plaintiffs’ Community, resulting in The County  
 17 having to repair and remake its infrastructure, property and systems that have been  
 18 damaged by Defendants’ action, including, *inter alia*, its property and systems to  
 19 treat addiction and abuse, to respond to and manage an elevated level of  
 20 emergencies and crime, and to respond to and treat injuries and process deaths in  
 21 Plaintiffs’ Community.

22 401. The County owns property which has been injuriously affected by the  
 23 public nuisance caused by Defendants. These property interests, include, *inter*  
 24 *alia*, additional naloxone doses – The County owns these doses which have been  
 25 and are destroyed when The County has to administer them to persons who are  
 26 overdosing as a result of Defendants’ intentional, unlawful, and reckless  
 27 manufacturing, marketing, distribution, promotion and sale of prescription  
 28 opioids. The County’s emergency response system and medical services

1 equipment and other materials will similarly need to be improved and replaced  
 2 because this property has been and is being damaged due to persons who are  
 3 overdosing as a result of Defendants' intentional, unlawful, and reckless  
 4 manufacturing, marketing, distribution, promotion and sale of prescription  
 5 opioids. The County also has damage to its property related to evidence gathering  
 6 and testing for the prosecution of drug related crimes.

7 402. In addition, The County has suffered damages to its infrastructure,  
 8 which will need to be retrofitted and repaired as a result of Defendants'  
 9 intentional, unlawful, and reckless manufacturing, marketing, distribution,  
 10 promotion and sale of prescription opioids. This damage includes damage to its  
 11 law enforcement, medical and rehabilitation infrastructures and systems which are  
 12 now inadequate to handle the new undue burden on these systems caused by  
 13 Defendants' conduct. This includes, *inter alia*, repairing and upgrading jail  
 14 facilities to add additional jail space and beds for opioid addicts who commit  
 15 crimes as well as retrofitting the facilities to treat inmates' addictions. This also  
 16 includes repairing and upgrading court systems for prosecution and defense of  
 17 drug-related crimes. This also includes repairing and upgrading hospital and  
 18 treatment facilities for members of Plaintiffs' Community addicted to opioids as  
 19 well as property that is part of and used by The County's Department of the  
 20 Medical Examiner which must investigate deaths known or suspected to be due to  
 21 drug intoxication.

22 403. The County owns, operates, manages, maintains, and otherwise has  
 23 property interests in, all of which have been injured, damaged, or affected by  
 24 Defendants, the following property:

- 25 a. County Jail system, including buildings, cells, beds, supplies,  
 26 resources, materials, personnel, equipment, and other property.
- 27 b. County Probation system, including offices, personnel, supplies,  
 28 resources, materials, equipment, and other property.

- c. County District Attorney system, including offices, personnel, supplies, resources, materials, equipment, and other property.
- d. County Health and Human Services system, including offices, personnel, supplies, resources, materials, equipment, and other property.
- e. County Sheriff and Law Enforcement systems, including Narcan, naloxone, offices, personnel, supplies, resources, materials, equipment, and other property.
- f. County Emergency Responder system, including equipment, Narcan, naloxone, materials, supplies, personnel, offices, and other property.
- g. County Public Health system, including offices, personnel, resources, supplies, equipment, materials, and other property.
- h. County Medical Examiner system, including personnel, offices, supplies, equipment, materials, resources, and other property.
- i. County Public Defender System, including personnel, offices, supplies, equipment, materials, resources, and other property.

404. As set forth above in allegations specifically incorporated herein, by selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a course of conduct that injuriously affects The County and its property.

405. The public nuisance caused by Defendants' affirmative promotion of opioids has caused substantial annoyance, inconvenience, and injury to The County and The County's property.

406. The acts by Defendants which have injured The County and its property are unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

1           407. Defendants have unlawfully and/or intentionally caused and  
2 permitted dangerous drugs under their control to be diverted such as to injure the  
3 County's property.

4           408. Defendants' conduct in illegally distributing and selling prescription  
5 opioids, or causing such opioids to be distributed and sold, where Defendants  
6 know, or reasonably should know, such opioids will be diverted and possessed  
7 and/or used illegally in Plaintiffs' Community is of a continuing nature and has  
8 produced a significant injury to The County and its property.

9           409. Defendants' ongoing conduct produces an ongoing nuisance.

10           410. Defendants know, or reasonably should know, that their conduct will  
11 have an ongoing detrimental effect upon The County and The County's property.

12           411. Defendants' actions were, at the least, a substantial factor causing the  
13 harm to The County and its property.

14           412. The presence of diverted prescription opioids in Plaintiffs'  
15 Community, and the consequence of prescription opioids having been diverted in  
16 Plaintiffs' Community, proximately results in and/or substantially contributes to  
17 the creation of significant past and future costs to The County as it must repair and  
18 retrofit its property in order to enforce the law and treat the victims of opioid  
19 abuse and addiction.

20           413. Defendants' conduct is a direct and proximate cause of and/or a  
21 substantial contributing factor to opioid addiction and abuse in Plaintiffs'  
22 Community, costs that will be borne by Plaintiffs' Community and The County.

23           414. As a direct and proximate result of Defendants' creation of a public  
24 nuisance, The County has suffered and continues to suffer damages to its property  
25 requiring investigation, repair, remediation, and other costs to be determined at  
26 trial.

27           415. The damages available to The County include, *inter alia*, recoupment  
28 of governmental costs, flowing from the damages to The County's property which



1 The County seeks to recover damages for. Defendants' conduct is ongoing and  
2 persistent, and The County seeks all damages flowing from Defendants' conduct.

3 416. As a direct result of Defendants' conduct, The County and Plaintiffs'  
4 Community have suffered actual injury and damages including, but not limited to,  
5 significant expenses for repairing and retrofitting property related to police,  
6 emergency, health, prosecution, corrections and other services. The County here  
7 seeks recovery for its own harm.

8 417. The County has sustained specific and special injuries because its  
9 damages include, *inter alia*, injury to the property and systems of its health  
10 services, law enforcement, and medical examiner, as well as property costs related  
11 to opioid addiction treatment and overdose prevention, as described in this  
12 Complaint.

13 418. The County seeks all legal and equitable relief as allowed by law,  
14 including *inter alia* compensatory damages, from the Defendants for the creation  
15 of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

### 16 **COUNT III**

#### 17 **RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT**

18 **18 U.S.C. § 1961, et seq.**

19 **(Against Defendants Purdue, Cephalon, Janssen, and Endo)**

20 **(The "Opioid Marketing Enterprise")**

21 419. Plaintiff, The County, incorporates by reference all other paragraphs  
22 of this Complaint as if fully set forth herein, and further alleges as follows.

23 420. Plaintiff, The County, brings this Count on behalf of itself against the  
24 following Defendants, as defined above: Purdue, Cephalon, Janssen, and Endo  
25 (referred to collectively for this Claim as the "RICO Marketing Defendants").

26 421. At all relevant times, the RICO Marketing Defendants were and are  
27 "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding,  
28 and do hold, "a legal or beneficial interest in property."

1           422. Section 1962(c) of RICO makes it unlawful “for any person  
2 employed by or associated with any enterprise engaged in, or the activities of  
3 which affect, interstate or foreign commerce, to conduct or participate, directly or  
4 indirectly, in the conduct of such enterprise’s affairs through a pattern of  
5 racketeering activity.” 18 U.S.C. § 1962(c).

6           423. The term “enterprise” is defined as including “any individual,  
7 partnership, corporation, association, or other legal entity, and any union or group  
8 of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4).  
9 The definition of “enterprise” in Section 1961(4) includes legitimate and  
10 illegitimate enterprises within its scope. Specifically, the section “describes two  
11 separate categories of associations that come within the purview of an ‘enterprise’  
12 -- the first encompassing organizations such as corporations, partnerships, and  
13 other ‘legal entities,’ and the second covering ‘any union or group of individuals  
14 associated in fact although not a legal entity.’” *United State v. Turkette*, 452 U.S.  
15 576, 577 (1981).

16           424. Beginning in the early 1990s, the RICO Marketing Defendants  
17 aggressively sought to bolster their revenue, increase profit, and grow their share  
18 of the prescription painkiller market by unlawfully increasing the volume of  
19 opioids they sold. The RICO Marketing Defendants knew that they could not  
20 increase their profits without misrepresenting that opioids were non-addictive and  
21 safe for the long-term treatment of chronic pain.

22           425. The generally accepted standards of medical practice prior to the  
23 1990s dictated that opioids should only be used in short durations to treat acute  
24 pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-  
25 life) care. Due to the evidence of addiction and lack of evidence indicating that  
26 opioids improved patients’ ability to overcome pain and function, the use of  
27 opioids for chronic pain was discouraged or prohibited. As a result, doctors  
28 generally did not prescribe opioids for chronic pain.

1           426. Knowing that their products were highly addictive, ineffective and  
 2 unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain,  
 3 the RICO Marketing Defendants formed an association-in-fact enterprise and  
 4 engaged in a scheme to unlawfully increase their profits and sales, and grow their  
 5 share of the prescription painkiller market, through repeated and systematic  
 6 misrepresentations about the safety and efficacy of opioids for treating long-term  
 7 chronic pain.

8           427. The RICO Marketing Defendants formed an association-in-fact  
 9 enterprise consisting of “advocacy groups and professional societies” (“Front  
 10 Groups”) and paid “physicians affiliated with these groups” (KOLs”) in order to  
 11 unlawfully increase the demand for opioids. Through their personal relationships,  
 12 the RICO Marketing Defendants and members of the Opioid Marketing Enterprise  
 13 had the opportunity to form and take actions in furtherance of the Opioid  
 14 Marketing Enterprise’s common purpose. The RICO Marketing Defendants’  
 15 substantial financial contribution to the Opioid Marketing Enterprise, and the  
 16 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.<sup>188</sup>

17           428. The RICO Marketing Defendants, through the Opioid Marketing  
 18 Enterprise, made misleading statements and misrepresentations about opioids that  
 19 downplayed the risk of addiction and exaggerated the benefits of opioid use,  
 20 including: (1) downplaying the serious risk of addiction; (2) creating and  
 21 promoting the concept of “pseudoaddiction” when signs of actual addiction began  
 22 appearing and advocated that the signs of addiction should be treated with more  
 23 opioids; (3) exaggerating the effectiveness of screening tools to prevent addiction;  
 24 (4) claiming that opioid dependence and withdrawal are easily managed; (5)

25  
 26  
 27 <sup>188</sup> *Fueling an Epidemic: Exposing the Financial Ties Between Opioid*  
 28 *Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security  
 & Governmental Affairs Committee, Ranking Members’ Office, February 12,  
 2018 <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at 1.

1 denying the risks of higher opioid dosages; and (6) exaggerating the effectiveness  
2 of “abuse-deterrent” opioid formulations to prevent abuse and addiction.

3 429. The RICO Marketing Defendants also falsely touted the benefits of  
4 long-term opioid use, including the supposed ability of opioids to improve  
5 function and quality of life, even though there was no scientifically reliable  
6 evidence to support the RICO Marketing Defendants’ claims.

7 430. The RICO Marketing Defendants’ scheme, and the common purpose  
8 of the Opioid Marketing Enterprise, has been wildly successful. Opioids are now  
9 the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in  
10 revenue for drug companies in 2010 alone; sales in the United States have  
11 exceeded \$8 billion in revenue annually since 2009.<sup>189</sup> In an open letter to the  
12 nation’s physicians in August 2016, the then-U.S. Surgeon General expressly  
13 connected this “urgent health crisis” to “heavy marketing of opioids to doctors . . .  
14 [m]any of [whom] were even taught – incorrectly – that opioids are not addictive  
15 when prescribed for legitimate pain.”<sup>190</sup>

16 431. The scheme devised and implemented by the RICO Marketing  
17 Defendants amounted to a common course of conduct designed to ensure that the  
18 RICO Marketing Defendants unlawfully increased their sales and profits through  
19 misrepresentations about the addictive nature and effective use of the RICO  
20 Marketing Defendants’ drugs. As Senator McCaskill aptly recognized:

21 The opioid epidemic is the direct result of a calculated marketing and  
22 sales strategy developed in the 90’s, which delivered three simple  
23 messages to physicians. First, that chronic pain was severely  
24 undertreated in the United States. Second, that opioids were the best  
tool to address that pain. And third, that opioids could treat pain

25 <sup>189</sup> See Katherine Eban, *OxyContin: Purdue Pharma’s Painful Medicine*, Fortune,  
26 Nov. 9, 2011, [http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/)  
27 [medicine/](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/); David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times,  
Aug. 10, 2016, [https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95)  
a121aa8abd95.

28 <sup>190</sup> Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016),  
<http://turnthetiderx.org/>; *Fueling An Epidemic*, *supra* n.3, at 1.

without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.<sup>191</sup>

**A. THE OPIOID MARKETING ENTERPRISE**

432. The Opioid Marketing Enterprise consists of the RICO Marketing Defendants, the Front Groups, and the KOLs – each of whom is identified below:

- The RICO Defendants
  - Purdue
  - Cephalon
  - Janssen
  - Endo
- The Front Groups
  - American Pain Foundation (“APF”)
  - American Academy of Pain Medicine (“AAPM”)
  - American Pain Society (“APS”)
  - Federation of State Medical Boards (“FSMB”)
  - U.S. Pain Foundation (“USPF”)
  - American Geriatrics Society (“AGS”)
- The KOLs
  - Dr. Russell Portenoy (“Dr. Portenoy”)
  - Dr. Lynn Webster (“Dr. Webster”)
  - Dr. Perry Fine (“Dr. Fine”)
  - Dr. Scott M. Fishman (“Dr. Fishman”))

433. The Opioid Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links, interpersonal relationships and engaged in a pattern of predicate acts (i.e. racketeering activity)

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<sup>191</sup> See, *LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*, September 12, 2017, at 31:03-31:37, [https://www.youtube.com/watch?v=k9mrQa8\\_vAo](https://www.youtube.com/watch?v=k9mrQa8_vAo) (accessed on March 1, 2018).

1 in order to further the common purpose of the enterprise: unlawfully increasing  
2 profits and revenues from the continued prescription and use of opioids for long-  
3 term chronic pain. Each of the individuals and entities who formed the Opioid  
4 Marketing Enterprise is an entity or person within the meaning of 18 U.S.C. §  
5 1961(3) and acted to enable the common purpose and fraudulent scheme of the  
6 Opioid Marketing Enterprise.

7 434. In order to accomplish the common purpose, members of the Opioid  
8 Marketing Enterprise repeatedly and systematically misrepresented –  
9 affirmatively, and through half-truths and omissions – that opioids are non-  
10 addictive and safe for the effective treatment of long-term, chronic, non-acute and  
11 non-cancer pain, and for other off-label uses not approved by the FDA. The  
12 Opioid Marketing Enterprise misrepresented and concealed the serious risks and  
13 lack of corresponding benefits of using opioids for long-term chronic pain. By  
14 making these misrepresentations, the Opioid Marketing Enterprise ensured that a  
15 large number of opioid prescriptions would be written and filled for chronic pain.

16 435. At all relevant times, the Opioid Marketing Enterprise: (a) had an  
17 existence separate and distinct from each RICO Marketing Defendant and its  
18 members; (b) was separate and distinct from the pattern of racketeering in which  
19 the RICO Defendants engaged; (c) was an ongoing and continuing organization  
20 consisting of individuals, persons, and legal entities, including each of the RICO  
21 Marketing Defendants; (d) was characterized by interpersonal relationships  
22 between and among each member of the Opioid Marketing Enterprise, including  
23 between the RICO Marketing Defendants and each of the Front Groups and  
24 KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f)  
25 functioned as a continuing unit.

26 436. The persons and entities engaged in the Opioid Marketing Enterprise  
27 are systematically linked through contractual relationships, financial ties, personal  
28



relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

437. Each of the RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. Each of the RICO Marketing Defendants coordinated their marketing efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise.

### **1. The RICO Defendants**

438. In addition to their systematic links to and personal relationships with the Front Groups and KOLS, described below, the RICO Marketing Defendants had systematic links to and personal relationships with each other through their participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities, including but not limited to, the Pain Care Forum (“PCF”) and the Healthcare Distribution Alliance (“HDA”).

439. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. Plaintiffs are informed and believe that the PCF was created with the stated goal of offering a “setting where multiple organizations can share information” and “promote and support taking collaborative action regarding federal pain policy issues.” Plaintiffs are informed and believe that past APF President Will Rowe described the PCF as “a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations.”

1           440. The PCF recently became a national news story when it was  
2 discovered that lobbyists for members of the PCF, including the RICO Marketing  
3 Defendants, quietly shaped federal and state policies regarding the use of  
4 prescription opioids for more than a decade.

5           441. The Center for Public Integrity and The Associated Press obtained  
6 “internal documents shed[ding] new light on how drug makers and their allies  
7 shaped the national response to the ongoing wave of prescription opioid abuse.”<sup>192</sup>  
8 Specifically, PCF members spent over \$740 million lobbying in the nation’s  
9 capital and in all 50 statehouses on an array of issues, including opioid-related  
10 measures.<sup>193</sup>

11           442. Not surprisingly, each of the RICO Marketing Defendants who stood  
12 to profit from lobbying in favor of prescription opioid use is a member of and/or  
13 participant in the PCF.<sup>194</sup> In 2012, membership and participating organizations in  
14 the PCF included the HDA (of which all the RICO Defendants are members),  
15 Endo, Purdue, Johnson & Johnson (the parent company for Janssen  
16 Pharmaceuticals), and Teva (the parent company of Cephalon).<sup>195</sup> Each of the  
17 RICO Marketing Defendants worked together through the PCF to advance the  
18 interests of the Opioid Marketing Enterprise. But, the RICO Marketing  
19 Defendants were not alone, many of the RICO Marketing Defendants’ Front  
20 Groups were also members of the PCF, including the American Academy of Pain  
21 Management, the American Pain Foundation, and the American Pain Society.

23 <sup>192</sup> Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug  
24 epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),  
25 [https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic)  
[shaped-policy-amid-drug-epidemic](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic) (emphasis added).

<sup>193</sup> *Id.*

26 <sup>194</sup> PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011),  
27 [https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf)  
[Meetings-Schedule-amp.pdf](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf) (last visited March 8, 2018).

28 <sup>195</sup> *Id.* Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

1 Upon information and belief, the RICO Marketing Defendants' KOLs were also  
2 members of and participated in the PCF.

3 443. Through the Pain Care Forum, the RICO Marketing Defendants met  
4 regularly and in person to form and take action to further the common purpose of  
5 the Opioid Marketing Enterprise and shape the national response to the ongoing  
6 prescription opioid epidemic.

7 444. Through the HDA – or Healthcare Distribution Alliance – the RICO  
8 Marketing Defendants “strengthen[ed] . . . alliances”<sup>196</sup> and took actions to further  
9 the common purpose of the Opioid Marketing Enterprise.

10 445. Beyond strengthening alliances, the benefits of HDA membership  
11 included the ability to, among other things, “network one on one with  
12 manufacturer executives at HDA’s members-only Business and Leadership  
13 Conference,” “participate on HDA committees, task forces and working groups  
14 with peers and trading partners,” and “make connections.”<sup>197</sup> Clearly,  
15 membership in the HDA was an opportunity to create interpersonal and ongoing  
16 organizational relationships and “alliances” between the RICO Marketing  
17 Defendants.

18 446. The closed meetings of the HDA’s councils, committees, task forces  
19 and working groups provided the RICO Marketing Defendants with the  
20 opportunity to work closely together, confidentially, to develop and further the  
21 common purpose and interests of the Opioid Marketing Enterprise.

22 447. The HDA also offered multiple conferences, including annual  
23 business and leadership conferences through which the RICO Marketing  
24 Defendants had an opportunity to “bring together high-level executives, thought  
25

26 <sup>196</sup> Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed  
27 on September 14, 2017),  
28 <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en> (emphasis added).

<sup>197</sup> *Id.*

1 leaders and influential managers . . . to hold strategic business discussions on the  
 2 most pressing industry issues.”<sup>198</sup> The HDA and its conferences were significant  
 3 opportunities for the RICO Marketing Defendants to interact at the executive level  
 4 and form and take actions in furtherance of the common purpose of the Opioid  
 5 Marketing Enterprise. It is clear that the RICO Marketing Defendants embraced  
 6 this opportunity by attending and sponsoring these events.<sup>199</sup>

7 448. The systematic contacts and personal relationships developed by the  
 8 RICO Marketing Defendants through the PCF and the HDA furthered the  
 9 common purpose of the Opioid Marketing Enterprise because it allowed the RICO  
 10 Marketing Defendants to coordinate the conduct of the Opioid Marketing  
 11 Enterprise by, including but not limited to, coordinating their interaction and  
 12 development of relationships with the Front Groups and KOLs.

## 13 **2. The Front Groups**

14 449. Each of the RICO Marketing Defendants had systematic links to and  
 15 personal relationships with Front Groups that operated as part of the Opioid  
 16 Marketing Enterprise to further the common purpose of unlawfully increasing  
 17 sales by misrepresenting the non-addictive and effective use of opioids for the  
 18 treatment of long-term chronic pain. As recently reported by the U.S. Senate in  
 19 “*Fueling an Epidemic*”:

20 The fact that these same manufacturers provided millions of dollars to  
 21 the groups described below suggests, at the very least, a direct link  
 22 between corporate donations and the advancement of opioids-friendly  
 23 messaging. By aligning medical culture with industry goals in this  
 24 way, many of the groups described in this report may have played a

25 <sup>198</sup> Business and Leadership Conference – Information for Manufacturers,  
 26 Healthcare Distribution Alliance<https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed on September 14, 2017).

27 <sup>199</sup> 2015 Distribution Management Conference and Expo, Healthcare Distribution  
 28 Alliance, <https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last accessed on September 14, 2017).

1           significant role in creating the necessary conditions for the U.S.  
2           opioids epidemic.<sup>200</sup>

3           450. “Patient advocacy organizations and professional societies like the  
4           Front Groups ‘play a significant role in shaping health policy debates, setting  
5           national guidelines for patient treatment, raising disease awareness, and educating  
6           the public.’”<sup>201</sup> “Even small organizations— with ‘their large numbers and  
7           credibility with policymakers and the public’—have ‘extensive influence in  
8           specific disease areas.’ Larger organizations with extensive funding and outreach  
9           capabilities ‘likely have a substantial effect on policies relevant to their industry  
10          sponsors.’”<sup>202</sup> Indeed, as reflected below, the U.S. Senate’s report found that the  
11         RICO Marketing Defendants made nearly \$9 million worth of contributions to  
12         various Front Groups, including members of the Opioid Marketing Enterprise.<sup>203</sup>

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26         <sup>200</sup> Fueling an Epidemic, at p. 1.

27         <sup>201</sup> *Id.* at p. 2

28         <sup>202</sup> *Id.*

<sup>203</sup> *Id.* at p. 3.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue <sup>22</sup>	Janssen <sup>23</sup>	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	\$1,091,024.86	\$128,000.00	\$43,491.95	\$3,050.00 <sup>24</sup>	\$0.00	\$1,265,566.81
American Academy of Pain Medicine	\$725,584.95	\$83,975.00	\$332,100.00	\$57,750.00	\$0.00	\$1,199,409.95
AAPM Foundation	\$0.00	\$0.00	\$304,605.00	\$0.00	\$0.00	\$304,605.00
ACS Cancer Action Network	\$168,500.00 <sup>25</sup>	\$0.00	\$0.00	\$0.00	\$0.00	\$168,500.00
American Chronic Pain Association	\$312,470.00	\$50,000.00	\$54,670.00	\$0.00	\$0.00	\$417,140.00
American Geriatrics Society	\$11,785.00 <sup>26</sup>	\$0.00	\$0.00	\$0.00	\$0.00	\$11,785.00
American Pain Foundation	\$25,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$25,000.00
American Pain Society	\$542,259.52	\$88,500.00	\$288,750.00	\$22,965.00	\$20,250.00	\$962,724.52
American Society of Pain Educators	\$30,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$30,000.00
American Society of Pain Management Nursing	\$242,535.00	\$55,177.85 <sup>27</sup>	\$25,500.00 <sup>28</sup>	\$0.00	\$0.00	\$323,212.85
The Center for Practical Bioethics	\$145,095.00	\$18,000.00	\$0.00	\$0.00	\$0.00	\$163,095.00
The National Pain Foundation <sup>29</sup>	\$0.00	\$0.00	\$0.00	\$562,500.00	\$0.00	\$562,500.00
U.S. Pain Foundation	\$359,300.00	\$41,500.00	\$22,000.00	\$2,500,000.00 <sup>30</sup>	\$0.00	\$2,922,800.00
Washington Legal Foundation	\$500,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$500,000.00
	<b>\$4,153,554.33</b>	<b>\$465,152.85</b>	<b>\$1,071,116.95</b>	<b>\$3,146,265.00</b>	<b>\$20,250.00</b>	<b>\$8,856,339.13</b>

451. The Front Groups included in the Opioid Marketing Enterprise “have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported



industry interests at the expense of their own constituencies.<sup>204</sup> And, as reflected below, many of the RICO Marketing Defendants' Front Groups received the largest contributions:

FIGURE 5: Group Rankings by Manufacturer Payments, 2012-2017

<b>U.S. Pain Foundation</b>	\$2,922,800.00
<b>Academy of Integrative Pain Management</b>	\$1,265,566.81
<b>American Academy of Pain Medicine</b>	\$1,199,409.95
<b>American Pain Society</b>	\$962,724.52
<b>The National Pain Foundation</b>	\$562,500.00
<b>Washington Legal Foundation</b>	\$500,000.00
<b>American Chronic Pain Association</b>	\$417,140.00
<b>American Society of Pain Management Nursing</b>	\$323,212.85
<b>AAPM Foundation</b>	\$304,605.00
<b>ACS Cancer Action Network</b>	\$168,500.00
<b>The Center for Practical Bioethics</b>	\$163,095.00
<b>American Society of Pain Educators</b>	\$30,000.00
<b>American Pain Foundation</b>	\$25,000.00
<b>American Geriatrics Society</b>	\$11,785.00

452. But, the RICO Marketing Defendants connection with and control over the Front Groups did not end with financial contributions. Rather, the RICO Marketing Defendants made substantial contributions to physicians affiliated with the Front Groups totaling more than \$1.6 million.<sup>205</sup> Moreover, the RICO Marketing Defendants "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.<sup>206</sup>

<sup>204</sup> *Id.* at p. 3.

<sup>205</sup> *Id.* at p. 3.

<sup>206</sup> *Id.* at p. 10.

453. As described in more detail below<sup>207</sup>, the RICO Marketing Defendants “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”<sup>208</sup> They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.”<sup>209</sup>

FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012-Present<sup>41</sup>

	Payments to Group	Payments to Group-Affiliated Individuals	Total
U.S. Pain Foundation	\$2,922,800.00	\$126.20	\$2,922,926.20
The National Pain Foundation	\$562,500.00	\$839,848.84	\$1,402,348.84
Academy of Integrative Pain Management	\$1,265,566.81	\$30,223.42	\$1,295,790.23
American Academy of Pain Medicine	\$1,199,409.95	\$16,462.42	\$1,215,872.37
American Pain Society	\$962,724.52	\$95,474.56	\$1,058,199.08
AAPM Foundation	\$304,605.00	\$314,175.58	\$618,780.58
Washington Legal Foundation	\$500,000.00	N/A	\$500,000.00
American Chronic Pain Association	\$417,140.00	\$31,265.87	\$448,405.87
American Society of Pain Management Nursing	\$323,212.85	N/A	\$323,212.85
American Society of Pain Educators	\$30,000.00	\$280,765.92	\$310,765.92
The Center for Practical Bioethics	\$163,095.00	\$7,116.86	\$170,211.86
ACS Cancer Action Network	\$168,500.00	N/A	\$168,500.00
American Pain Foundation	\$25,000.00	N/A	\$25,000.00
American Geriatrics Society	\$11,785.00	\$194.13	\$11,979.13
<b>Total</b>	<b>\$8,856,339.13</b>	<b>\$1,615,653.80</b>	<b>\$10,471,992.93</b>

<sup>207</sup> The activities that the Front Groups engaged in, and the misrepresentations that they made, in furtherance of the common purpose of the Opioid Marketing Enterprise are alleged more fully below, under the heading “Conduct of the Opioid Marketing Enterprise.”

<sup>208</sup> *Id.* at 12-15.

<sup>209</sup> *Id.* at 12.

1           454. The systematic contacts and interpersonal relationships of the RICO  
2 Marketing Defendants, and the Front Groups are further described below:

3           455. The American Pain Foundation (“APF”) – The American Pain  
4 Foundation was the most prominent member of the RICO Defendants’ Front  
5 Groups and was funded almost exclusively by the RICO Marketing Defendants.  
6 Plaintiffs are informed and believe that APF received more than \$10 million in  
7 funding from the RICO Marketing Defendants between 2007 and the close of its  
8 business in May 2012. The APF had multiple contacts and personal relationships  
9 with the RICO Marketing Defendants through its many publishing and  
10 educational programs, funded and supported by the RICO Marketing Defendants.  
11 Plaintiffs are further informed and believe that between 2009 and 2010, APF  
12 received more than eighty percent (80%) of its operating budget from  
13 pharmaceutical industry sources. Including industry grants for specific projects,  
14 APF received about \$2.3 million from industry sources out of total income of  
15 about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9  
16 million from drug companies, out of total income of about \$3.5 million. By 2011,  
17 upon information and belief, APF was entirely dependent on incoming grants  
18 from Defendants Purdue, Cephalon, Endo, and others.

19           456. On information and belief, APF was often called upon to provide  
20 “patient representatives” for the RICO Marketing Defendants’ promotional  
21 activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s  
22 Talk Pain.” APF functioned largely as an advocate for the interests of the RICO  
23 Marketing Defendants, not patients. Indeed, upon information and belief, as early  
24 as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to  
25 “strategically align its investments in nonprofit organizations that share [its]  
26 business interests.”

27           457. APF is also credited with creating the PCF in 2004. Plaintiffs are  
28 informed and believe that the PCF was created with the stated goal of offering a

1 “setting where multiple organizations can share information” and “promote and  
 2 support taking collaborative action regarding federal pain policy issues.”  
 3 Plaintiffs are informed and believe that past APF President Will Rowe described  
 4 the PCF as “a deliberate effort to positively merge the capacities of industry,  
 5 professional associations, and patient organizations.”

6 458. Upon information and belief, representatives of the RICO Marketing  
 7 Defendants, often at informal meetings at conferences, suggested activities and  
 8 publications for APF to pursue. APF then submitted grant proposals seeking to  
 9 fund these activities and publications, knowing that drug companies would  
 10 support projects conceived as a result of these communications.

11 459. Furthermore, APF’s Board of Directors was largely comprised of  
 12 doctors who were on Defendants’ payrolls, either as consultants or speakers at  
 13 medical events.<sup>210</sup> As described below, many of the KOLs involved in the Opioid  
 14 Marketing Enterprise also served in leadership positions within the APF.

15 460. In December 2011, a ProPublica investigation found that in 2010,  
 16 nearly 90% of APF’s funding came from the drug and medical device community,  
 17 including RICO Marketing Defendants.<sup>211</sup> More specifically, APF received  
 18 approximately \$2.3 million from industry sources out of total income of \$2.85  
 19 million in 2009. It’s budget for 2010 projected receipt of approximately \$2.9  
 20 million from drug companies, out of total income of approximately \$3.5 million.  
 21 In May 2012, the U.S. Senate Finance Committee began looking into APF to  
 22 determine the links, financial and otherwise, between the organization and the  
 23 manufacturers of opioid painkillers. Within days of being targeted by the Senate  
 24

25 <sup>210</sup> Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica  
 26 (Dec. 23, 2011), <https://www.propublica.org/article/the-champion-of-painkillers>.

27 <sup>211</sup> Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of*  
 28 *painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011),  
[https://www.washingtonpost.com/national/healthscience/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probefinds/2011/12/20/gIQAgvczDP\\_story.html?utm\\_term=.22049984c606](https://www.washingtonpost.com/national/healthscience/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probefinds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606).

1 investigation, APF's Board voted to dissolve the organization "due to irreparable  
2 economic circumstances." APF "cease[d] to exist, effective immediately."<sup>212</sup>

3 461. The American Academy of Pain Medicine ("AAPM") – The AAPM  
4 was another Front Group that had systematic ties and personal relationships with  
5 the RICO Defendants. AAPM received over \$2.2 million in funding since 2009  
6 from opioid manufacturers. AAPM maintained a corporate relations council,  
7 whose members paid \$25,000 per year (on top of other funding) to participate.  
8 The benefits included allowing members to present educational programs at off-  
9 site dinner symposia in connection with AAPM's marquee event – its annual  
10 meeting held in Palm Springs, California, or other resort locations. AAPM  
11 describes the annual event as an "exclusive venue" for offering education  
12 programs to doctors. Membership in the corporate relations council also allowed  
13 drug company executives and marketing staff to meet with AAPM executive  
14 committee members in small settings. The RICO Marketing Defendants were all  
15 members of the council and presented deceptive programs to doctors who  
16 attended this annual event.<sup>213</sup>

17 462. The RICO Marketing Defendants internally viewed AAPM as  
18 "industry friendly," with RICO Defendants' advisors and speakers among its  
19 active members. The RICO Marketing Defendants attended AAPM conferences,  
20 funded its CMEs and satellite symposia, and distributed its publications. AAPM  
21 conferences heavily emphasized sessions on opioids. AAPM presidents have  
22 included top industry-supported KOLs like Perry Fine and Lynn Webster.

23  
24  
25 <sup>212</sup> Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies'*  
26 *Ties to Pain Groups*, Wash. Post, May 8, 2012,  
27 [https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU\\_story.html](https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html).

28 <sup>213</sup> The American Academy of Pain Medicine, *Pain Medicine DC The Governing*  
*Voices of Pain: Medicine, Science, and Government*, March 24-27, 2011,  
<http://www.painmed.org/files/2011-annual-meeting-program-book.pdf>.

1           463. Upon information and belief, representatives of the RICO Marketing  
2 Defendants, often at informal meetings at conferences, suggested activities and  
3 publications for AAPM to pursue. AAPM then submitted grant proposals seeking  
4 to fund these activities and publications, knowing that drug companies would  
5 support projects conceived as a result of these communications.

6           464. Plaintiffs are informed and believe that members of AAPM's Board  
7 of Directors were doctors who were on the RICO Marketing Defendants' payrolls,  
8 either as consultants or speakers at medical events. As described below, many of  
9 the KOLs involved in the Opioid Marketing Enterprise also served in leadership  
10 positions within the AAPM.

11           465. The American Pain Society ("APS") – The APS was another Front  
12 Group with systematic connections and interpersonal relationships with the RICO  
13 Marketing Defendants. APS was one of the Front Groups investigated by  
14 Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising  
15 out of their investigation of "extensive ties between companies that manufacture  
16 and market opioids and non-profit organizations" that "helped created a body of  
17 dubious information favoring opioids."<sup>214</sup>

18           466. Upon information and belief, representatives of the RICO Marketing  
19 Defendants, often at informal meetings at conferences, suggested activities and  
20 publications for APS to pursue. APS then submitted grant proposals seeking to  
21 fund these activities and publications, knowing that drug companies would  
22 support projects conceived as a result of these communications.

23           467. Plaintiffs are informed and believe that members of APS's Board of  
24 Directors were doctors who were on the RICO Marketing Defendants' payrolls,

25  
26  
27 <sup>214</sup> Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine  
28 Underwood, Executive Director (May 8, 2012), American Pain Society,  
<https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf>.



1 either as consultants or speakers at medical events. As described below, many of  
 2 the KOLs involved in the Opioid Marketing Enterprise also served in leadership  
 3 positions within the APS.

4 468. The Federation of State Medical Boards (“FSMB”) – FSMB was  
 5 another Front Group with systematic connections and interpersonal relationships  
 6 with the RICO Marketing Defendants. In addition to the contributions reported in  
 7 *Fueling an Epidemic*, a June 8, 2012 letter submitted by FSMB to the Senate  
 8 Finance Committee disclosed substantial payments from the RICO Marketing  
 9 Defendants beginning in 1997 and continuing through 2012.<sup>215</sup> Not surprisingly,  
 10 the FSMB was another one of the Front Groups investigated by Senators Grassley  
 11 and Baucus, as evidenced by their May 8, 2012 letter arising out of their  
 12 investigation of “extensive ties between companies that manufacture and market  
 13 opioids and non-profit organizations” that “helped created a body of dubious  
 14 information favoring opioids.”<sup>216</sup>

15 469. The U.S. Pain Foundation (“USPF”) – The USPF was another Front  
 16 Group with systematic connections and interpersonal relationships with the RICO  
 17 Marketing Defendants. The USPF was one of the largest recipients of  
 18 contributions from the RICO Marketing Defendants, collection nearly \$3 million  
 19 in payments between 2012 and 2015 alone.<sup>217</sup> The USPF was also a critical  
 20 component of the Opioid Marketing Enterprise’s lobbying efforts to reduce the  
 21 limits on over-prescription. The U.S. Pain Foundation advertises its ties to the  
 22 RICO Marketing Defendants, listing opioid manufacturers like Pfizer, Teva,  
 23

24 <sup>215</sup> June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators  
 25 Max Baucus and Charles Grassley.

26 <sup>216</sup> Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine  
 27 Underwood, Executive Director (May 8, 2012), American Pain Society,  
 28 <https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf>.

<sup>217</sup> *Fueling an Epidemic*, at p. 4.

1 Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as “Platinum,”  
 2 “Gold,” and “Basic” corporate members.<sup>218</sup> Industry Front Groups like the  
 3 American Academy of Pain Management, the American Academy of Pain  
 4 Medicine, the American Pain Society, and PhRMA are also members of varying  
 5 levels in the USPF.

6 470. American Geriatrics Society (“AGS”) – The AGS was another Front  
 7 Group with systematic connections and interpersonal relationships with the RICO  
 8 Defendants. The AGS was a large recipient of contributions from the RICO  
 9 Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted  
 10 with the RICO Marketing Defendants to disseminate guidelines regarding the use  
 11 of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older  
 12 Persons, hereinafter “2002 AGS Guidelines”) and 2009 (Pharmacological  
 13 Management of Persistent Pain in Older Persons,<sup>219</sup> hereinafter “2009 AGS  
 14 Guidelines”). According to news reports, AGS has received at least \$344,000 in  
 15 funding from opioid manufacturers since 2009.<sup>220</sup> AGS’s complicity in the  
 16 common purpose of the Opioid Marketing Enterprise is evidenced by the fact that  
 17 AGS internal discussions in August 2009 reveal that it did not want to receive-up  
 18 front funding from drug companies, which would suggest drug company  
 19 influence, but would instead accept commercial support to disseminate pro-opioid  
 20 publications.

21 471. Upon information and belief, representatives of the RICO Marketing  
 22 Defendants, often at informal meetings at conferences, suggested activities,

24 <sup>218</sup> *Id.* at 12; Transparency, U.S. Pain Foundation,  
 25 <https://uspainfoundation.org/transparency/> (last accessed on March 9, 2018).

26 <sup>219</sup> *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am.  
 27 Geriatrics Soc’y 1331, 1339, 1342 (2009), available at  
 28 <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

<sup>220</sup> John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

1 lobbying efforts and publications for AGS to pursue. AGS then submitted grant  
2 proposals seeking to fund these activities and publications, knowing that drug  
3 companies would support projects conceived as a result of these communications.

4 472. Plaintiffs are informed and believe that members of AGS Board of  
5 Directors were doctors who were on the RICO Marketing Defendants' payrolls,  
6 either as consultants or speakers at medical events. As described below, many of  
7 the KOLs involved in the Opioid Marketing Enterprise also served in leadership  
8 positions within the AGS.

9 473. There was regular communication between each of the RICO  
10 Marketing Defendants, Front Groups and KOLs, in which information was shared,  
11 misrepresentations were coordinated, and payments were exchanged. Typically,  
12 the coordination, communication and payment occurred, and continues to occur,  
13 through the use of the wires and mail in which the RICO Markets Defendants,  
14 Front Groups, and KOLs share information necessary to overcome objections and  
15 resistance to the use of opioids for chronic pain. The RICO Marketing  
16 Defendants, Front Groups and KOLs functioned as a continuing unit for the  
17 purpose of implementing the Opioid Marketing Enterprise's scheme and common  
18 purpose, and each agreed to take actions to hide the scheme and continue its  
19 existence.

20 474. At all relevant times, the Front Groups were aware of the RICO  
21 Marketing Defendants' conduct, were knowing and willing participants in that  
22 conduct, and reaped benefits from that conduct. Each Front Group also knew, but  
23 did not disclose, that the other Front Groups were engaged in the same scheme, to  
24 the detriment of consumers, prescribers, and The County. But for the Opioid  
25 Marketing Enterprise's unlawful fraud, the Front Groups would have had  
26 incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid  
27 Marketing Enterprise to their members and constituents. By failing to disclose  
28

1 this information, Front Groups perpetuated the Opioid Marketing Enterprise's  
2 scheme and common purpose, and reaped substantial benefits.

### 3 **3. The KOLs**

4 475. Similarly, each of the RICO Marketing Defendants financed,  
5 supported, utilized and relied on the same KOLs by paying, financing, supporting,  
6 managing, directing, or overseeing, and/or relying on their work. On Information  
7 and belief, the RICO Marketing Defendants cultivated this small circle of doctors  
8 solely because they favored the aggressive treatment of chronic pain with opioids.

9 476. The RICO Marketing Defendants and the Opioid Marketing  
10 Enterprise relied on their KOLs to serve as part of their speakers bureaus and to  
11 attend programs with speakers bureaus. The RICO Marketing Defendants graded  
12 their KOLs on performance, post-program sales, and product usage. Furthermore,  
13 the RICO Marketing Defendants expected their KOLs to stay "on message," and  
14 obtained agreements from them, in writing, that "all slides must be presented in  
15 their entirety and without alterations . . . and in sequence."

16 477. The RICO Marketing Defendants' KOLs have been at the center of  
17 the Opioid Marketing Enterprise's marketing efforts, presenting the false  
18 appearance of unbiased and reliable medical research supporting the broad use of  
19 opioid therapy for chronic pain. As described in more detail below, the KOLs  
20 have written, consulted, edited, and lent their names to books and articles, and  
21 given speeches, and CMEs supporting chronic opioid therapy. They have served  
22 on committees that developed treatment guidelines that strongly encourage the use  
23 of opioids to treat chronic pain (even while acknowledging the lack of evidence in  
24 support of that position) and on the boards of the pro-opioid Front Groups  
25 identified above.

26 478. The RICO Marketing Defendants and KOLS all had systematic  
27 connections and interpersonal relationships, as described below, through the  
28 KOLs receipt of payments from the RICO Marketing Defendants and Front

1 Groups, the KOLs' authoring, publishing, speaking, and educating on behalf of  
 2 the RICO Marketing Defendants, and their leadership roles and participation in  
 3 the activities of the Front Groups, which were in turn financed by the RICO  
 4 Marketing Defendants.

5 479. The systematic contacts and interpersonal relationships of the KOLs  
 6 with the RICO Marketing Defendants and Front Groups are described below:

7 480. Dr. Russell Portenoy – Dr. Portenoy was one of the main KOLs that  
 8 the RICO Marketing Defendants identified and promoted to further the common  
 9 purpose of the Opioid Marketing Enterprise. Dr. Portenoy received research  
 10 support, consulting fees, and honoraria from the RICO Defendants, and was a paid  
 11 consultant to various RICO Marketing Defendants. Dr. Portenoy was  
 12 instrumental in opening the door for the regular use of opioids to treat chronic  
 13 pain. Dr. Portenoy is credited as one of the authors on a primary pillar of the  
 14 RICO Marketing Defendants' misrepresentation regarding the risks and benefits  
 15 of opioid use.<sup>221</sup> Dr. Portenoy had financial relationships with at least a dozen  
 16 pharmaceutical companies, most of which produced prescription opioids.<sup>222</sup>

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18  
 19 <sup>221</sup> In 1986, the medical journal *Pain*, which would eventually become the official  
 20 journal of the American Pain Society ("APS"), published an article by Portenoy  
 21 and Foley summarizing the results of a "study" of 38 chronic non-cancer pain  
 22 patients who had been treated with opioid painkillers. Portenoy and Foley  
 23 concluded that, for non-cancer pain, opioids "can be safely and effectively  
 24 prescribed to selected patients with relatively little risk of producing the  
 25 maladaptive behaviors which define opioid abuse." However, their study was  
 26 neither scientific nor did it meet the rigorous standards commonly used to evaluate  
 the validity and strength of such studies in the medical community. For instance,  
 there was no placebo control group, and the results were retroactive (asking  
 patients to describe prior experiences with opioid treatment rather than less biased,  
 in-the-moment reports). The authors themselves advised caution, stating that the  
 drugs should be used as an "alternative therapy" and recognizing that longer term  
 studies of patients on opioids would have to be performed. None were. See Russell  
 K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-  
 malignant pain: report of 38 cases*, 25(2) *Pain* 171-86 (May 1986).

27 <sup>222</sup> Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got*  
 28 *Hooked, and Why It's So Hard to Stop*, (Johns Hopkins University Press 2016), at  
 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and*  
*Death* (St. Martin's Press, 1st Ed 2003).

1           481. In exchange for the payments he received from the RICO Marketing  
 2 Defendants, Dr. Portenoy is credited as one of the authors on a primary pillar of  
 3 the RICO Marketing Defendants' misrepresentation regarding the risks and  
 4 benefits of opioids.<sup>223</sup> Dr. Portenoy, published, spoke, consulted, appeared in  
 5 advertisements and on television broadcasts, and traveled the country to travel the  
 6 country to promote more liberal prescribing for many types of pain and conduct  
 7 continuing medical education ("CME") seminars sponsored by the RICO  
 8 Marketing Defendants and Front Groups.

9           482. Dr. Portenoy was also a critical component of the RICO Marketing  
 10 Defendants' control over their Front Groups, and the Front Groups support of the  
 11 Opioid Marketing Enterprise's common purpose. Specifically, Dr. Portenoy sat as  
 12 a Director on the board of the APF. He was also the President of the APS.

13           483. In a 2011 interview released by Physicians for Responsible Opioid  
 14 Prescribing, Dr. Portenoy admitted that his earlier work relied on evidence that  
 15 was not "real" and left real evidence behind, all in furtherance of the Opioid  
 16 Marketing Enterprise's common purpose:

17           I gave so many lectures to primary care audiences in which the Porter  
 18 and Jick article was just one piece of data that I would then cite, and I  
 19 would cite six, seven, maybe ten different avenues of thought or  
 20 avenues of evidence, none of which represented real evidence, and yet  
 what I was trying to do was to create a narrative so that the primary

21 <sup>223</sup> In 1986, the medical journal Pain, which would eventually become the official  
 22 journal of the American Pain Society ("APS"), published an article by Portenoy  
 23 and Foley summarizing the results of a "study" of 38 chronic non-cancer pain  
 24 patients who had been treated with opioid painkillers. Portenoy and Foley  
 25 concluded that, for non-cancer pain, opioids "can be safely and effectively  
 26 prescribed to selected patients with relatively little risk of producing the  
 27 maladaptive behaviors which define opioid abuse." However, their study was  
 28 neither scientific nor did it meet the rigorous standards commonly used to evaluate  
 the validity and strength of such studies in the medical community. For instance,  
 there was no placebo control group, and the results were retroactive (asking  
 patients to describe prior experiences with opioid treatment rather than less biased,  
 in-the-moment reports). The authors themselves advised caution, stating that the  
 drugs should be used as an "alternative therapy" and recognizing that longer term  
 studies of patients on opioids would have to be performed. None were. See Russell  
 K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-  
 malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).



1 care audience would look at this information in [total] and feel more  
 2 comfortable about opioids in a way they hadn't before. In essence this  
 was education to destigmatize [opioids], and because the primary goal  
 was to destigmatize, we often left evidence behind.<sup>224</sup>

3 484. Dr. Lynn Webster – Dr. Webster was a critical component of the  
 4 Opioid Marketing Enterprise, including advocating the RICO Marketing  
 5 Defendants' fraudulent messages regarding prescription opioids and had  
 6 systematic contacts and personal relationships with the RICO Marketing  
 7 Defendants and the Front Groups.

8 485. Dr. Webster was the co-founder and Chief Medical Director of an  
 9 otherwise unknown pain clinic in Salt Lake City, Utah (Lifetree Clinical  
 10 Research), who went on to become one of the RICO Marketing Defendants' main  
 11 KOLs. Dr. Webster was the President of American Academy of Pain Medicine  
 12 ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that  
 13 published Endo special advertising supplements touting Opana ER. Dr. Webster  
 14 was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At  
 15 the same time, Dr. Webster was receiving significant funding from the RICO  
 16 Marketing Defendants (including nearly \$2 million from Cephalon alone).

17 486. During a portion of his time as a KOL, Dr. Webster was under  
 18 investigation for overprescribing by the U.S. Department of Justice's Drug  
 19 Enforcement Agency, which raided his clinic in 2010. Although the investigation  
 20 was closed without charges in 2014, more than twenty (20) of Dr. Webster's  
 21 former patients at the Lifetree Clinic have died of opioid overdoses.

22 487. Dr. Webster created and promoted the Opioid Risk Tool, a five  
 23 question, one-minute screening tool relying on patient self-reports that purportedly  
 24 allows doctors to manage the risk that their patients will become addicted to or  
 25 abuse opioids. The claimed ability to pre-sort patients likely to become addicted is  
 26

27 <sup>224</sup> Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube  
 28 (Oct. 30, 2011),  
<https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

1 an important tool in giving doctors confidence to prescribe opioids long-term, and,  
 2 for this reason, references to screening appear in various industry-supported  
 3 guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked  
 4 to, websites run by Endo, Janssen, and Purdue.

5 488. Dr. Webster is also credited as one of the leading proponents of  
 6 "pseudoaddiction" that the RICO Marketing Defendants, Front Groups and KOLs  
 7 disseminated as part of the common purpose of the Opioid Marketing Enterprise.

8 489. Plaintiff The County is informed and believes that in exchange for  
 9 the payments he received from the RICO Marketing Defendants, Dr. Webster  
 10 published, spoke, consulted, appeared in advertisements and on television  
 11 broadcasts, and traveled the country to promote more liberal prescribing of  
 12 opioids for many types of pain and conduct CME seminars sponsored by the  
 13 RICO Marketing Defendants and Front Groups.

14 490. Like Dr. Portenoy, Dr. Webster later reversed his opinion and  
 15 disavowed his previous work on and opinions regarding pseudoaddiction.  
 16 Specifically, Dr. Webster acknowledged that "[pseudoaddiction] obviously  
 17 became too much of an excuse to give patients more medication."<sup>225</sup>

18 491. Dr. Perry Fine – Dr. Webster was a critical component of the Opioid  
 19 Marketing Enterprise, including advocating the RICO Marketing Defendants'  
 20 fraudulent messages regarding prescription opioids and had systematic contacts  
 21 and personal relationships with the RICO Marketing Defendants and the Front  
 22 Groups.

23 492. Dr. Fine was originally a doctor practicing in Utah, who received  
 24 support from the RICO Marketing Defendants, including Janssen, Cephalon,  
 25 Endo, and Purdue. Dr. Fine's ties to the RICO Marketing Defendants have been  
 26

27 <sup>225</sup> John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J.  
 28 Sentinel, Feb. 18, 2012,  
<http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

1 well documented.<sup>226</sup> He has authored articles and testified in court cases and  
 2 before state and federal committees, and he served as president of the AAPM, and  
 3 argued against legislation restricting high-dose opioid prescription for non-cancer  
 4 patients. Multiple videos featured Fine delivering educational talks about  
 5 prescription opioids. He even testified in a trial that the 1,500 pills a month  
 6 prescribed to celebrity Anna Nicole Smith for pain did not make her an addict  
 7 before her death.<sup>227</sup> He has also acknowledged having failed to disclose numerous  
 8 conflicts of interest.

9 493. Dr. Fine was also a critical component of the RICO Marketing  
 10 Defendants' control over their Front Groups, and the Front Groups support of the  
 11 Opioid Marketing Enterprise's common purpose. Specifically, Dr. Fine served on  
 12 the Board of Directors of APF and served as the President of the AAPM in 2011.

13 494. Plaintiff The County is informed and believes that in exchange for  
 14 the payments he received from the RICO Marketing Defendants, Dr. Fine  
 15 published, spoke, consulted, appeared in advertisements and on television  
 16 broadcasts, and traveled the country to promote more liberal prescribing of  
 17 opioids for many types of pain and conduct CME seminars sponsored by the  
 18 RICO Marketing Defendants and Front Groups.

19 495. Dr. Scott M. Fishman – Dr. Fishman was a critical component of the  
 20 Opioid Marketing Enterprise, including advocating the RICO Marketing  
 21 Defendants' fraudulent messages regarding prescription opioids and had  
 22  
 23

24  
 25 <sup>226</sup> Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long*  
 26 *Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM),  
[https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-](https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry)  
[to-drug-industry](https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry)

27 <sup>227</sup> Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle  
 28 Times (Sept. 22, 2010, 5:16 PM),  
[http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-](http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smithwas-addicted/)  
[smithwas-addicted/](http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smithwas-addicted/).

1 systematic contacts and personal relationships with the RICO Marketing  
2 Defendants and the Front Groups.

3 496. Although Dr. Fishman did not receive direct financial payments from  
4 the RICO Marketing Defendants, his ties to the opioid drug industry are legion.<sup>228</sup>

5 497. As Dr. Fishman's personal biography indicates, he is critical  
6 component of the RICO Marketing Defendants' control over their Front Groups,  
7 and the Front Groups support of the Opioid Marketing Enterprise's common  
8 purpose. Specifically, Dr. Fishman is an "internationally recognized expert on  
9 pain and pain management" who has served in "numerous leadership roles with  
10 the goal to alleviate pain."<sup>229</sup> Dr. Fishman's roles in the pain industry include  
11 "past president of the American Academy of Pain Medicine [AAPM], past  
12 chairman of the board of directors of the American Pain Foundation [APF], and  
13 past board member of the American Pain Society [APS]."<sup>230</sup> Dr. Fishman is also  
14 "the immediate past chair and current member of the Pain Care Coalition of the  
15 American Society of Anesthesiologists, American Pain Society, and Academy of  
16 Pain Medicine."<sup>231</sup> Dr. Fishman's leadership positions within the central core of  
17 the RICO Marketing Defendants' Front Groups was a direct result of his  
18 participation in the Opioid Marketing Enterprise and agreement to cooperate with  
19 the RICO Marketing Defendants' pattern of racketeering activity.

20 498. Plaintiff The County is informed and believes that in exchange for  
21 the payments he received from the RICO Marketing Defendants, Dr. Fishman  
22 published, spoke, consulted, appeared in advertisements and on television  
23

24 \_\_\_\_\_  
25 <sup>228</sup> Scott M. Fishman, M.D., Professor, U.C. Davis Health, Center for Advancing  
26 Pain Relief,  
27 [https://www.ucdmc.ucdavis.edu/advancingpainrelief/our\\_team/Scott\\_Fishman.htm](https://www.ucdmc.ucdavis.edu/advancingpainrelief/our_team/Scott_Fishman.html)  
28 l (accessed on February 28, 2018).

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

1 broadcasts, and traveled the country to promote more liberal prescribing of  
2 opioids for many types of pain and conduct CME seminars sponsored by the  
3 RICO Marketing Defendants and Front Groups.

4 499. There was regular communication between each of the RICO  
5 Marketing Defendants, Front Groups and KOLs, in which information was shared,  
6 misrepresentations are coordinated, and payments were exchanged. Typically, the  
7 coordination, communication and payment occurred, and continues to occur,  
8 through the use of the wires and mail in which the RICO Marketing Defendants,  
9 Front Groups, and KOLs share information regarding overcoming objections and  
10 resistance to the use of opioids for chronic pain. The RICO Marketing  
11 Defendants, Front Groups and KOLs functioned as a continuing unit for the  
12 purpose of implementing the Opioid Marketing Enterprise's scheme and common  
13 purpose, and each agreed to take actions to hide the scheme and continue its  
14 existence.

15 500. At all relevant times, the KOLs were aware of the RICO Marketing  
16 Defendants' conduct, were knowing and willing participants in that conduct, and  
17 reaped benefits from that conduct. The RICO Marketing Defendants selected  
18 KOLs solely because they favored the aggressive treatment of chronic pain with  
19 opioids. The RICO Marketing Defendants' support helped the KOLs become  
20 respected industry experts. And, as they rose to prominence, the KOLs falsely  
21 touted the benefits of using opioids to treat chronic pain, repaying the RICO  
22 Marketing Defendants by advancing their marketing goals. The KOLs also knew,  
23 but did not disclose, that the other KOLs and Front Groups were engaged in the  
24 same scheme, to the detriment of consumers, prescribers, and The County. But  
25 for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have  
26 had incentive to disclose the deceit by the RICO Marketing Defendants and the  
27 Opioid Marketing Enterprise, and to protect their patients and the patients of other  
28 physicians. By failing to disclose this information, KOLs furthered the Opioid

1 Marketing Enterprise's scheme and common purpose, and reaped substantial  
2 benefits.

3 501. As public scrutiny and media coverage focused on how opioids  
4 ravaged communities in California and throughout the United States, the Front  
5 Groups and KOLS did not challenge the RICO Marketing Defendants'  
6 misrepresentations, seek to correct their previous misrepresentations, terminate  
7 their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks  
8 of using opioids for chronic pain outweighed their benefits and were not supported  
9 by medically acceptable evidence.

10 502. The RICO Marketing Defendants, Front Groups and KOLs engaged  
11 in certain discrete categories of activities in furtherance of the common purpose of  
12 the Opioid Marketing Enterprise. As reported in *Fueling an Epidemic*, the Opioid  
13 Marketing Enterprise's conduct in furtherance of the common purpose of the  
14 Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk  
15 of addiction and safe use of prescription opioids for long-term chronic pain; (2)  
16 lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or  
17 undermine CDC guidelines; and (4) efforts to limit prescriber accountability. The  
18 misrepresentations made in these publications are described in the following  
19 section.

20 503. Efforts to Minimize the Risk of Addiction and Promote Opioid Use  
21 As Safe for Long-Term Treatment of Chronic Pain – Members of the Opioid  
22 Marketing Enterprise furthered the common purpose of the enterprise by  
23 publishing and disseminating statements that minimized the risk of addiction and  
24 misrepresented the safety of using prescription opioids for long-term treatment of  
25 chronic, non-acute, and non-cancer pain. The categories of misrepresentations  
26  
27  
28



made by the Opioid Marketing Enterprise and the RICO Defendants included the following:<sup>232</sup>

- The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society, 13 Clinical J. Pain 6 (1997). The “landmark consensus” was published by the AAPM and APS. Dr. Portenoy was the sole consultant. A member of Purdue’s speaker bureau authored the consensus.
- *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (1998, 2004, 2007).<sup>233</sup> These guidelines, originally published by the FSMB in collaboration with RICO Defendants, advocated that opioids were “essential” and that “misunderstanding of addiction” contributed to undertreated pain.
- *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions, Testimony by John D. Giglio, M.A., J.D., Executive Direction of the APF* (2002.)<sup>234</sup>
- *The Management of Persistent Pain in Older Persons* (2002). These guidelines were published by AGS with substantial funding from Endo, Purdue and Janssen.
- *Overview of Management Options* (2003, 2007, 2010, and 2013).<sup>235</sup> This CME was edited by Dr. Portenoy, sponsored by Purdue, and published by

<sup>232</sup> As noted below, the earliest misrepresentations disseminated by the RICO Defendants and the Opioid Marketing Enterprise began in 1997 and has continued unabated since that time. Therefore, this list is alleged as fully and completely as possible.

<sup>233</sup> *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Federation of State Medical Boards of the United States, May 2004, [https://www.ihs.gov/painmanagement/includes/themes/newihstheme/display\\_objects/documents/modelpolicytreatmentpain.pdf](https://www.ihs.gov/painmanagement/includes/themes/newihstheme/display_objects/documents/modelpolicytreatmentpain.pdf) (last accessed on March 9, 2018).

<sup>234</sup> *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions, Testimony by John D. Giglio, M.A., J.D., Executive Direction of the APF* (2002.)

the American Medical Association. It taught that opioids, unlike non-prescription pain medication are safe at high doses.

- *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004).<sup>236</sup> This article, published by Endo Pharmaceuticals advocated that withdrawal and needing to take higher dosages are not signs of addiction.
- Interview by Paula Moyer with Scott M. Fishman, M.D. (2005). Dr. Fishman advocated that “the risks of addiction are . . . small and can be managed.”<sup>237</sup>
- Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results (2006).<sup>238</sup> Dr. Webster gave this CME, sponsored by Cephalon, that misrepresented that opioids were safe for the treatment of non-cancer pain.
- *Treatment Options: A Guide for People Living With Pain* (2007). This document was published by the APF and sponsored by Cephalon and Purdue.<sup>239</sup>

<sup>235</sup> Portenoy, et al., *Overview of Management Options*, <https://cme.ama-assn.org/activity/1296783/detail.aspx>. On information and belief, this CME was published by the American Medical Association in 2003, 2007, 2010, and 2013.

<sup>236</sup> Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), <https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics> (last accessed March 8, 2018).

<sup>237</sup> Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

<sup>238</sup> Hale ME, Webster LR, Peppin JF, Messina J. Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results. Program and abstracts of the annual meeting of the American Academy of Pain Medicine; February 22-25, 2006; San Diego, California. Abstract 120. Published with permission of Lynn R. Webster, MD, [https://www.medscape.org/viewarticle/524538\\_2](https://www.medscape.org/viewarticle/524538_2) (accessed on March 6, 2018).

<sup>239</sup> Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed on March 8, 2018).

- 1 • *Responsible Opioid Prescribing: A Physician's Guide* (2007).<sup>240</sup> This  
2 book, authored by Dr. Fishman was financed by the FSMB with funding  
3 from Cephalon, Endo and Purdue.
- 4 • *Avoiding Opioid Abuse While Managing Pain* (2007).<sup>241</sup> This book, co-  
5 authored by Dr. Webster, misrepresented that for prescribers facing signs of  
6 aberrant behavior, increasing the dose in "most cases . . . should be a  
7 clinician's first response."
- 8 •  *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version*  
9 *1.0-SF* (2008).<sup>242</sup> This screening tool was published by the National  
10 Institutes of Health with support from Endo through an educational grant,  
11 and advocated that most patients are able to successfully remain on long-  
12 term opioid therapy without significant problems.
- 13 • *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*  
14 (2007).<sup>243</sup> This article, sponsored by Endo, misrepresented that opioids are  
15 a highly effective class of analgesic drugs.
- 16 • *Opioid-Based Management of Persistent and Breakthrough Pain* (2008).<sup>244</sup>  
17 This document was written by Dr. Fine and sponsored by an educational

20 <sup>240</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9  
21 (Waterford Life Sciences 2007).

22 <sup>241</sup> Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*  
(2007).

23 <sup>242</sup> *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-*  
24 *SF*, PainEdu.org, 2008, [https://www.nhms.org/sites/default/files/Pdfs/SOAPP-](https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf)  
5.pdf (last accessed on March 8, 2018).

25 <sup>243</sup> Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for*  
26 *Chronic Pain*, Pain Med. News,  
[https://www.painmedicine.com/download/BtoB\\_Opana\\_WM.pdf](https://www.painmedicine.com/download/BtoB_Opana_WM.pdf) (last visited  
on March 8, 2018).

27 <sup>244</sup> Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and*  
28 *Breakthrough Pain*, Pain Medicine News,  
[https://www.yumpu.com/en/document/view/11409251/opioid-based-management-](https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain)  
of-persistent-and-breakthrough-pain (accessed on February 27, 2018).

1 grant from Cephalon. Dr. Fine advocated for the prescription of rapid onset  
2 opioids “in patients with non-cancer pain.”

- 3 • *Optimizing Opioid Treatment for Breakthrough Pain* (2008).<sup>245</sup> Dr.  
4 Webster presented an online seminar (webinar) sponsored by Cephalon, that  
5 misrepresented that non-opioid analgesics and combination opioids  
6 containing non-opioids are less effective because of dose limitations.
- 7 • *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-*  
8 *Cancer Pain* (2009).<sup>246</sup> These guidelines were published by AAPM and  
9 APS. Fourteen of the twenty-one panel members, including Dr. Portenoy  
10 and Dr. Fine, received support from the RICO Defendants.
- 11 • *Pharmacological Management of Persistent Pain in Older Persons*  
12 (2009).<sup>247</sup> These guidelines were published by AGS, with substantial  
13 funding from Endo, Purdue, and Janssen, updated the 2002 guidelines and  
14 misrepresented that the risks of addiction are exceedingly low.
- 15 • Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit  
16 Wounds: A Survival Guide to Pain Management for Returning Veterans  
17 and Their Families,<sup>248</sup> American Pain Foundation, 2009. This article was  
18 published in 2009 and sponsored by Purdue.

19  
20  
21 <sup>245</sup> Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape,  
[http://www.medscape.org/viewarticle/563417\\_6](http://www.medscape.org/viewarticle/563417_6) (last visited Dec. 11, 2017).

22 <sup>246</sup> Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in*  
*Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

23 <sup>247</sup> *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am.  
24 Geriatrics Soc’y 1331, 1339, 1342 (2009), available at  
[https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-](https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf)  
25 [PainGuidelines2009.pdf](https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf) (last accessed on March 9, 2018).

26 <sup>248</sup> Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit  
27 Wounds: A Survival Guide to Pain Management for Returning Veterans and Their  
28 Families, Coalition for Iraq + Afghanistan Veterans,  
<http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families> (last visited March 1, 2018)

- 1 • *Finding Relief: Pain Management for Older Adults*, (2009).<sup>249</sup> This article  
2 was a collaboration between the American Geriatrics Society, AAPM and  
3 Janssen.
- 4 • Good Morning America (2010). Dr. Portenoy appeared on Good Morning  
5 America and stated that “Addiction, when treating pain, is distinctly  
6 uncommon.”<sup>250</sup>
- 7 • *A Policymaker’s Guide to Understanding Pain & Its Management*,  
8 *American Pain Foundation* (2011).<sup>251</sup> APF published this document, that  
9 was sponsored by Purdue, which argued that the notion of strong pain  
10 leading to addiction is a common misconception.
- 11 • *Managing Patient’s Opioid Use: Balancing the Need and the Risk*  
12 (2011).<sup>252</sup> Dr. Webster presented a webinar, sponsored by Purdue, that  
13 misrepresented the ability to use risk screen tools, urine samples and patient  
14 agreements to prevent overuse and overdose death.
- 15 • *Safe and Effective Opioid Rotation* (2012).<sup>253</sup> This CME, delivered by Dr.  
16 Fine, that is also available online, advocated for the safe and non-addictive  
17 use of opioids to treat cancer and non-cancer patients over a person’s  
18 “lifetime.”

21 <sup>249</sup> *Finding Relief, Pain Management for Older Adults*, (2009).

22 <sup>250</sup> Good Morning America (ABC television broadcast Aug. 30, 2010).

23 <sup>251</sup> *A Policymaker’s Guide to Understanding Pain & Its Management*, American  
Pain Foundation (2011) at

24 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>  
(last visited March 6, 2018).

25 <sup>252</sup> *See, Managing Patient’s Opioid Use: Balancing the Need and the Risk*,  
26 Emerging Solutions in Pain [http://www.emergingsolutionsinpain.com/ce-education/opioid-](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209)  
27 [management?option=com\\_continued&view=frontmatter&Itemid=303&course=20](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209)  
9 (last visited Aug. 22, 2017).

28 <sup>253</sup> Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012),  
[https://www.youtube.com/watch?v=\\_G3II9yqgXI](https://www.youtube.com/watch?v=_G3II9yqgXI).

- *Pain: Opioid Facts* (2012).<sup>254</sup> This document was published online on Endo's website [painknowledge.org](http://www.painknowledge.org) and advocated for the use of opioids and downplayed the risk of addiction, even for people with a history of addiction and opioid use, and supported the concept of pseudoaddiction.

504. Efforts to Criticize or Undermine CDC Guidelines – Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which represented “an important step – and perhaps the first major step from the federal government – toward limiting opioid prescriptions for chronic pain.” The following are examples of the actions taken by Opioid Marketing Enterprise members to prevent restriction on over-prescription:

- Several Front Groups, including the U.S. Pain Foundation, and the AAPM criticized the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”<sup>255</sup>
- The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”<sup>256</sup>

<sup>254</sup> *Pain: Opioid Facts*, [http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380\\_b385%20%20pf%20opiod.pdf](http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf) (last visited March 6, 2018).

<sup>255</sup> Pat Anson, *Chronic Pain Group Blasts CDC for Opioid Guidelines*, Pain News Networks, <https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines> (last accessed on March 8, 2018).

<sup>256</sup> Practical Pain Management, Responses and Criticisms Over New CDC Opioid Prescribing Guidelines (<https://www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines>) (accessed Sept. 28, 2017).



1           505. In each of the actions performed by members of the Opioid  
2 Marketing Enterprise, described above, the members of the Opioid Marketing  
3 Enterprise made branded and unbranded marketing claims about prescription  
4 opioids that misrepresented prescription opioids as non-addictive and safe for use  
5 as identified in following section.

6                           **4. Members of the Opioid Marketing Enterprise**  
7                           **Furthered the Common Purpose by Making**  
8                           **Misrepresentations.**

9           506. The RICO Marketing Defendants, Front Groups and KOLs  
10 participated in the conduct of the Opioid Marketing Enterprise and shared in the  
11 common purpose of marketing opioids for chronic pain through a pattern of  
12 racketeering activity (including multiple instances of mail and wire fraud) by  
13 knowingly making material misrepresentations or omissions to California  
14 prescribers, consumers, the general public, regulators and The County. All of the  
15 misrepresentations made by members of the Opioid Marketing Enterprise  
16 furthered the common purpose of the Enterprise.

17           507. Members of the Opioid Marketing Enterprise, including the RICO  
18 Marketing Defendants, Front Groups and KOLs made multiple unbranded  
19 marketing misrepresentations about the benefits and risks of opioid use, in  
20 furtherance of the Opioid Marketing Enterprise's common purpose, as follows:

21           508. Members of the Opioid Marketing Enterprise minimized the risks of  
22 addiction and/or construed opioids as non-addictive:

- 23           • AAMP and APS endorsed the use of opioids to treat chronic pain and  
24           claimed that the risk of a patients' addiction to opioids was low.<sup>257</sup>

25  
26  
27  
28           <sup>257</sup> The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement  
From the American Academy of Pain Medicine and the American Pain Society, 13  
Clinical J. Pain 6 (1997).

- 1 • “[O]pioids are safe and effective, and only in rare cases lead to  
2 addiction.”<sup>258</sup>

- 3 • “[T]he risks of addiction are . . . small and can be managed.”<sup>259</sup>

4 **Medscape: Controversy surrounds both the undertreatment and overtreatment**  
5 **of pain. Overtreatment of pain obviously involves the fear of causing or**  
6 **perpetuating opioid drug dependency. What recommendations can you give to**  
7 **primary care physicians who are reluctant to prescribe opioids, either as**  
8 **adjuncts or primary agents for pain control, because of these fears?**

9 **Dr. Fishman:** It used to be that when you had a patient with pain and you were  
10 worried about giving him or her a drug that may be abusable or may cause  
11 addiction, the safest thing to do was nothing, as though doing nothing would have  
12 no risks in and of itself. We know that the risks of addiction are there, but they are  
13 small and can be managed. The AAPM is going to be at the forefront, educating

- 14 • Represented that calling opioids “‘narcotics’ reinforces myths and  
15 misunderstandings as it places emphasis on their potential abuse rather than  
16 on the importance of their use as pain medicines.”<sup>260</sup>

- 17 • “Addiction, when treating pain, is distinctly uncommon. If a person does  
18 not have a history, a personal history, of substance abuse, and does not have  
19 a history in the family of substance abuse, and does not have a very major  
20 psychiatric disorder, most doctors can feel very assured that that person is  
21 not going to become addicted.”<sup>261</sup>

#### 22 **OPIOID ANALGESICS (NARCOTICS)**

23 Opioid analgesics are another important class of medications that are very effective pain  
24 relievers. As mentioned before, they may also be called “narcotics.” Unfortunately, this  
25 term is used by law enforcement to refer to drugs that are abused. Cocaine and heroin  
26 are called narcotics even though they are very different kinds of drugs. Calling opioid  
27 analgesics “narcotics” reinforces myths and misunderstandings as it places emphasis on  
28 their potential abuse rather than on the importance of their use as pain medicines. In  
the pain treatment world, the word opioid is used when speaking about this class of  
medications.

23 <sup>258</sup> *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health,*  
24 *Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John  
25 D. Giglio, M.A., J.D., Executive Director, American Pain Foundation),  
26 <https://www.help.senate.gov/imo/media/doc/Giglio.pdf>.

25 <sup>259</sup> Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of  
26 Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ.  
27 of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

27 <sup>260</sup> APF, *Treatment Options*,  
28 <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last  
accessed on March 8, 2018).

<sup>261</sup> Good Morning America (ABC television broadcast Aug. 30, 2010).

- 1 • The risk of addiction is manageable for patients regardless of past abuse  
2 histories.<sup>262</sup>
- 3 • “[T]he likelihood that the treatment of pain using an opioid drug which is  
4 prescribed by a doctor will lead to addiction is extremely low.”<sup>263</sup>
- 5 • Patients might experience withdrawal symptoms associated with physical  
6 dependence as the decrease their dose, “[b]ut unlike actual addicts, such  
7 individuals, if they resume their opioid use, will only take enough  
8 medication to alleviate their pain.”<sup>264</sup>
- 9 • The notion that “strong pain medication leads to addiction” is a “common  
10 misconception.”<sup>265</sup>

### SOME COMMON MISCONCEPTIONS ABOUT PAIN

Use of strong pain medication leads to addiction. Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit [www.painsafe.org](http://www.painsafe.org).

<sup>262</sup> Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain, 10 J. Pain 113 (2009).

<sup>263</sup> Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

<sup>264</sup> Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

<sup>265</sup> A Policymaker’s Guide to Understanding Pain & Its Management, American Pain Foundation (2011) at 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited March 6, 2018).

- “Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain, maybe just to escape your problems.”<sup>266</sup>

*How can I be sure I’m not addicted?*

- ◆ Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain, maybe just to escape from your problems.
- ◆ Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

- Even for patients assessed to have a risk of abuse, “it does not mean that opioid use will become problematic or that opioids are contraindicated.”<sup>267</sup>

**WILL I BECOME ADDICTED TO OPIOIDS?**

This is a key issue for both you and your doctor to discuss. In general, people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted. However, patients who misuse or abuse opioids can become addicted to them, so openly discussing your concerns with your doctor is important. People who are addicted to opioids crave the “unusually happy” effect the drug has on them (a “buzz” or “high”) and will continue to use the drug even though it harms them.

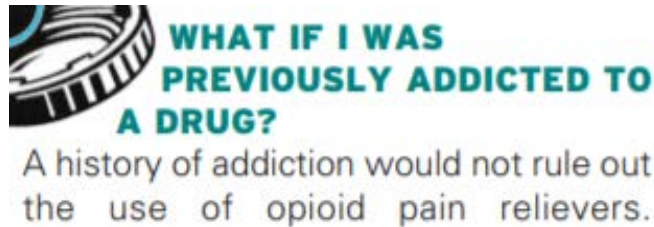


<sup>266</sup> Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), <https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics> (last accessed March 8, 2018).

<sup>267</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life Sciences 2007).



- [P]eople who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.”<sup>268</sup>
- “A history of addiction would not rule out the use of opioid pain relievers.”<sup>269</sup>



- APF published exit wounds, wherein it represented that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.”<sup>270</sup>

#### Iraq War Veteran Amputee, Pain Advocate and New Author Releases Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families



*"It's now four years since I lay in the dirt, near death, on the side of the road in Fallujah. I'm grateful for all the things I have, and proud of all I've accomplished. In the end though, I don't measure how far I've come by goals achieved, or academic degrees earned, or running trophies won. For me, what counts is that pain no longer rules my life."* – Derek McGinnis

The American Pain Foundation (APF) announces the release of Iraq War Veteran and Pain Advocate Derek McGinnis' first book, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*. Written in collaboration with nationally renowned pain experts, the release date of September 21 for Exit Wounds coincided with September's designation as Pain Awareness Month.

- Patients rarely become addicted to prescribed opioids.<sup>271</sup>

<sup>268</sup> *Pain: Opioid Facts*, [http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380\\_b385%20%20pf%20opioid.pdf](http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380_b385%20%20pf%20opioid.pdf) (last visited March 6, 2018).

<sup>269</sup> *Id.*

<sup>270</sup> Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families, Coalition for Iraq + Afghanistan Veterans, <http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families> (last visited March 1, 2018).

- Concern about patients becoming addicted reflects widespread failure to appreciate the distinction between “(1) *tolerance* – the body’s tendency to become accustomed to a substance so that, over time, a larger amount is needed to produce the same physical effect (pain relief) and *physical dependence* – the state defined by the experience of adverse symptoms if a drug is abruptly withdrawn . . . each of which is common with pain patients” . . . “and, on the other hand, (2) the psychological and behavioral patterns – an unhealthy craving for, compulsive use of, and unhealthy fixation – that characterize *addiction*.”<sup>272</sup>
- Evidence establishes that the risk of drug addiction (historically the principal *medical* justification for withholding or limiting opioids) is far *less* substantial than long and widely assumed.<sup>273</sup>

the addiction. Although the risks are exceedingly low in older patients with no current or past history of substance abuse, it is impossible to identify every patient who will abuse or divert prescribed opioids.<sup>117</sup> Therefore, many clinicians have adopted a Universal Precautions approach to pain management.<sup>118</sup> This paradigm stresses that every pa-

- The “risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.”<sup>274</sup>

<sup>271</sup> Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, \*9 (citing Portenoy, Russell, et al., *Acute and Chronic Pain*, in *COMPREHENSIVE TEXTBOOK OF SUBSTANCE ABUSE*, 863-903 (Lowinson et al. eds., 4th ed. 2005), *United States v. Hurowitz*, 459 F.3d 463 (2006) (citing Portenoy et. al, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, PAIN, Vol. 25, 171-186, (1986)).

<sup>272</sup> Brief of Amici Russel K. Portenoy, et al., 2005 WL 2405249, *United States v. Hurwitz*, 459 F.3d 463 (2006) (emphasis in original).

<sup>273</sup> *Id.* and sources cited at note 9.

<sup>274</sup> *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).



509. Members of the Opioid Marketing Enterprise advocated that opioids were safe and effective for long-term treatment of chronic, non-acute and non-cancer pain:

- “Opioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma. They may also be an important part of the management of persistent pain unrelated to cancer.”<sup>275</sup>

***Clinical uses***

Opioids are an essential option for treating moderate to severe pain associated with surgery or trauma, and for pain related to cancer. They may also be an important part of the management of persistent pain unrelated to cancer. These medicines block pain

- Opioids were a safe and effective treatment for of pain as part of a physicians’ treatment guidelines.<sup>276</sup>
- The “small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients.”<sup>277</sup>
- Opioids, unlike some non-prescription pain medications, are safe at high doses.<sup>278</sup>
- Falsely representing “recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems.”<sup>279</sup>

<sup>275</sup> APF, *Treatment Options*, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

<sup>276</sup> Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

<sup>277</sup> Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

<sup>278</sup> Portenoy, et al., *Overview of Management Options*, <https://cme.ama-assn.org/activity/1296783/detail.aspx>. On information and belief, this CME was published in 2003, 2007, 2010, and 2013.

<sup>279</sup> *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF*, PainEdu.org, 2008, <https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf> (last accessed on March 8, 2018).

- 1 • Opioid therapy is an appropriate treatment for chronic, non-cancer pain and  
2 integral to good medical practice.<sup>280</sup>
- 3 • Even for patients assessed to have a risk of abuse, “it does not mean that  
4 opioid use will become problematic or that opioids are contraindicated.”<sup>281</sup>
- 5 • Opioid therapy is an appropriate treatment for chronic, non-cancer pain and  
6 integral to good medical practice.<sup>282</sup>
- 7 • Broadly classifying pain syndromes as “either cancer- or non-cancer-related  
8 has limited utility,” and recommended dispensing rapid onset opioids “in  
9 patients with non-cancer pain.”<sup>283</sup>
- 10 The data suggest that FEBT is safe and well tolerated in opioid-tolerant patients  
11 with chronic noncancer pain. There was no respiratory depression, and a low  
12 incidence of treatment-related adverse events was reported. Thirty-five patients  
13 (37%) reported having at least 1 adverse event, the most common of which were  
14 nausea (7%) and dizziness (5%).
- 15 • Opioids are safe and well-tolerated in patients with chronic pain and break  
16 through pain.<sup>284</sup>
- 17 • Non-opioid analgesics and combination opioids containing non-opioids  
18 such as aspirin and acetaminophen are less effective than opioids because of  
19 dose limitations on non-opioids.<sup>285</sup>

20 <sup>280</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9  
(Waterford Life Sciences 2007).

21 <sup>281</sup> *Id.*

22 <sup>282</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life  
23 Sciences 2007).

24 <sup>283</sup> Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and*  
*Breakthrough Pain*, Pain Medicine News,  
25 [https://www.yumpu.com/en/document/view/11409251/opioid-based-management-](https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain)  
of-persistent-and-breakthrough-pain (accessed on February 27, 2018).

26 <sup>284</sup> Hale ME, Webster LR, Peppin JF, Messina J. Open-label study of fentanyl  
effervescent buccal tablets in patients with chronic pain and breakthrough pain:  
27 interim safety and tolerability results. Program and abstracts of the annual meeting  
of the American Academy of Pain Medicine; February 22-25, 2006; San Diego,  
28 California. Abstract 120. Published with permission of Lynn R. Webster, MD,  
[https://www.medscape.org/viewarticle/524538\\_2](https://www.medscape.org/viewarticle/524538_2) (accessed on March 6, 2018).

adverse events. Furthermore, although nonopioid analgesics, such as acetaminophen and NSAIDs/COX-2 inhibitors, are effective for nociceptive pain, their use in BTP is likewise restricted by dose-limiting toxicities, an onset of action that is delayed by 30 minutes or more, a long duration of action that could augment sedation and other side effects of the agent used for the baseline pain, and fears about renal and cardiovascular complications. Agents that combine an SAO, such as hydrocodone plus acetaminophen, aspirin, or ibuprofen, also are limited by potential adverse events and ceiling effects from the nonopioid component.

- Opioids can safely alleviate chronic pain unresponsive to other medication.<sup>286</sup>
- Medical organization and government-sponsored clinical guidelines support and encourage opioid treatment for chronic pain.<sup>287</sup>
- Respiratory depression, even at extremely high levels, does not occur in the context of appropriate clinical treatment.<sup>288</sup>
- There is no “ceiling dose” for opioids.<sup>289</sup>
- Opioid analgesics are the most effective way to treat pain of moderate to severe intensity and often the only treatment that provides significant relief.<sup>290</sup>
- “Opioid rotations” (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, may need to occur four or five times over a person’s “lifetime” to manage pain.<sup>291</sup>

<sup>285</sup> Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, [http://www.medscape.org/viewarticle/563417\\_6](http://www.medscape.org/viewarticle/563417_6) (last visited Dec. 11, 2017).

<sup>286</sup> Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, \*8, *United States v. Hurowitz*, 459 F.3d 463 (2006) (citing Portenoy et. al, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, PAIN, Vol. 25, 171-186, (1986)).

<sup>287</sup> *Id.* at \*8, and sources cited in note 11.

<sup>288</sup> *Id.*

<sup>289</sup> *Id.*

<sup>290</sup> Brief of Amici Russel K. Portenoy, et al., 2005 WL 2405249, *United States v. Hurwitz*, 459 F.3d 463.

- Opioids represent a highly effective . . . class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.<sup>292</sup>

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids—the gradual waning of relief at a given dose—and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.<sup>3</sup>

510. Members of the Opioid Marketing Enterprise created and championed the concept of “pseudoaddiction,” advocating that signs of addiction were actually pseudoaddiction that required prescribing additional opioids:

<sup>291</sup> Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), [https://www.youtube.com/watch?v=\\_G3II9yqgXI](https://www.youtube.com/watch?v=_G3II9yqgXI).

<sup>292</sup> Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, 2007, [https://www.painmedicineneeds.com/download/BtoB\\_Opana\\_WM.pdf](https://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf) (last visited on March 8, 2018).

## WHAT SHOULD I KNOW ABOUT OPIOIDS AND ADDICTION?

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You or your family may have questions about addiction. It is important to understand what addiction is. Addiction **IS** a chronic brain disease that can occur in some people exposed to certain substances such as alcohol, cocaine, and opioids. Taking opioids for pain relief is not addiction. People addicted to opioids crave the opioid and use it regularly for reasons other than pain relief.

Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.

- Patients might experience withdrawal symptoms associated with physical dependence as they decrease their dose, "[b]ut unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain."<sup>293</sup>
- "Addiction **IS NOT** when a person develops 'withdrawal' (such as abdominal cramping or sweating) after the medicine is stopped or the dose

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<sup>293</sup> Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, Howland v. Purdue Pharma, L.P., et al., Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.



1 is reduced by a large amount. . . . Addiction also **IS NOT** what happens  
 2 when some people taking opioids need to take a higher dose after a period  
 3 of time in order for it to continue to relieve their pain. This normal  
 4 ‘tolerance’ to opioid medications doesn’t affect everyone who takes them  
 5 and does not, by itself, imply addiction.”<sup>294</sup>

- 6 • Addiction to an opioid would mean that your pain has gone away but you  
 7 still take the medicine regularly when you don’t need it for pain, maybe just  
 8 to escape your problems.”<sup>295</sup>

9 *How can I be sure I’m not addicted?*

- 10 ♦ Addiction to an opioid would mean that  
 11 your pain has gone away but you still  
 12 take the medicine regularly when you  
 13 don’t need it for pain, maybe just to  
 14 escape from your problems.
- 15 ♦ Ask yourself: Would I want to take this  
 16 medicine if my pain went away? If you  
 17 answer no, you are taking opioids for  
 18 the right reasons—to relieve your pain  
 19 and improve your function. You are not  
 20 addicted.

- 21 • Behaviors such as “[r]equesting [drugs] by name,” “[d]emanding or  
 22 manipulative behavior,” “[o]btaining drugs from more than one physician,”  
 23 and “[h]oarding opioids,” are all really signs of pseudoaddiction, rather than  
 24 genuine addiction.”<sup>296</sup>
- 25 • “Sometimes people behave as if they are addicted, when they are really in  
 26 need of more medication.”<sup>297</sup>

27 <sup>294</sup> Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral*  
 28 *Opioid Analgesics*, Endo Pharmaceuticals (2004),  
[http://www.thblack.com/links/RSD/Understand\\_Pain\\_Opioid\\_Analgesics.pdf](http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf)  
 (emphasis in original) (last accessed on March 9, 2018).

<sup>295</sup> *Id.*

<sup>296</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9  
 (Waterford Life Sciences 2007).

<sup>297</sup> *Pain: Opioid Facts*,  
<http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patie>



- **ADDICTION** - A craving that drives a person to take an opioid even though it causes harm. This is a problem that needs immediate treatment. This happens to some patients who use opioids.

Sometimes people behave as if they are addicted, when they are really in need of more medication. This can be treated with higher doses of medicine.

- For prescribers facing signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”<sup>298</sup>

511. Members of the Opioid Marketing Enterprise advocated that long-term use of prescription opioids would improve function, including but not limited to, psychological health, and health-related quality of life:

Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain<sup>12</sup>

nted/pdf/Patient%20Education%20b380\_b385%20%20pf%20opiod.pdf (last visited March 6, 2018).

<sup>298</sup> Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

- 1 • When opioids are managed, properly prescribed and taken as directed, they
- 2 are effective in improving daily function, psychological health and health-
- 3 related quality of life.<sup>299</sup>
- 4 • Opioid therapy to relieve Membpain and improve function is a legitimate
- 5 medical practice for acute and chronic pain of both cancer and non-cancer
- 6 origins.<sup>300</sup>
- 7 • “[Y]our level of function should improve, you may find you are now able to
- 8 participate in activities of daily living, such as work and hobbies, that you
- 9 were not able to enjoy when your pain was worse.”<sup>301</sup>
- 10 • “The goal of opioid therapy is to . . . improve your function.”<sup>302</sup>
- 11 **The goal of opioid therapy is to control pain and improve your function.**
- 12
- 13 • The “goal” for chronic pain patients is to “improve effectiveness which is
- 14 different from efficacy and safety.”<sup>303</sup>

20 <sup>299</sup> A Policymaker’s Guide to Understanding Pain & Its Management, American  
 21 Pain Foundation (2011) at  
 22 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>  
 (last visited March 6, 2018).

23 <sup>300</sup> Scott M. Fishman, Responsible Opioid Prescribing: A Physician’s Guide, 8-9  
 (Waterford Life Sciences 2007); Scott M. Fishman, *Responsible Opioid*  
 24 *Prescribing: A Clinician’s Guide*, 10-11 (2d ed. 2012).

25 <sup>301</sup> Plaintiffs are informed and believe that this misrepresentation was made on the  
 website [painknowledge.org](http://www.painknowledge.org).

26 <sup>302</sup> *Pain: Opioid Facts*,  
[http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patie](http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf)  
 27 [nted/pdf/Patient%20Education%20b380\\_b385%20%20pf%20opiod.pdf](http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf) (last  
 visited March 6, 2018).

28 <sup>303</sup> Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012),  
[https://www.youtube.com/watch?v=\\_G3II9yqgXI](https://www.youtube.com/watch?v=_G3II9yqgXI).



512. Members of the Opioid Marketing Enterprise represented that screening questions and professional guidelines would help curb addiction and potential abuse:

- Screening questions and professional guidelines will “easily and efficiently” allow physicians to manage risk and “minimize the potential for abuse.”<sup>304</sup>
- Risk screening tools, urine testing, and patient agreements are a way to prevent “overuse of prescriptions” and “overdose deaths.”<sup>305</sup>

<sup>304</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life Sciences 2007).

<sup>305</sup> See, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*, Emerging Solutions in Pain [http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com\\_continued&view=frontmatter&Itemid=303&course=209](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209) (last visited Aug. 22, 2017).

## Program Overview

Compliance with regulatory and policy-driven authorities mandates improvement in the treatment of patients on chronic opioid therapy (COT) to ensure that the best possible care is provided to pain patients while minimizing potential risk of inappropriate use. Participants of this activity will be able to evaluate current issues in appropriate patient selection and management of chronic pain patients treated with COT including a review of the most current Risk Evaluation and Mitigation Strategies (REMS) requirements, updates in the development of novel delivery systems and the practical application of assessment tools to assist in their daily practice.

- The risks of addiction and abuse can be managed by doctors and evaluated with “tools.”<sup>306</sup>

513. In addition to the unbranded marketing misrepresentations made by members of the Opioid Marketing Enterprise, the RICO Marketing Defendants made misrepresentations in their branded marketing activities. The RICO Marketing Defendants’ branded marketing misrepresentations furthered the common purpose of the Opioid Marketing Enterprise because they advanced the common messages of the Opioid Marketing Enterprise. For example:

514. The RICO Marketing Defendants misrepresented that opioids were non-addictive or posed less risk of addiction or abuse:

- Purdue:
  - “Fear of addiction is exaggerated.”<sup>307</sup>

<sup>306</sup> Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), [https://www.youtube.com/watch?v=\\_G3II9yqgXI](https://www.youtube.com/watch?v=_G3II9yqgXI).

<sup>307</sup> Harriet Ryan, et al., “*You Want A Description of Hell?*” *OxyContin’s 12-Hour Problem*, L.A. Times (May 5, 2016), <http://documents.latimes.com/oxycontin-press-release-1996/> (hereinafter “Ryan, Description of Hell”).

The fear of addiction is exaggerated.  
One cause of patient resistance to appropriate pain treatment – the fear of addiction – is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief."

Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

- "[W]e've discovered that the simplicity and convenience of twice-daily dosing also enhances patient compliance with their doctor's instructions."<sup>308</sup>

taking tablets every four to six hours. Moreover, we've discovered that the simplicity and convenience of twice-daily dosing also enhances

[https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23\\_T23962617276&format=GNBF](https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23_T23962617276&format=GNBF)

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patient compliance with their doctor's instructions."

- Long-acting, extended release formulations are safe and "less prone" to abuse by patients and addiction.<sup>309</sup>
- OxyContin is safe and non-addictive when using extended release formulations, and appropriate for use in non-cancer patients.<sup>310</sup>

<sup>308</sup> *Id.*

<sup>309</sup> Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. Times (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html> (hereinafter "Meier, Guilty Plea").

<sup>310</sup> Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), [http://www.opb.org/news/article/america\\_pain\\_foundation\\_shuts\\_down\\_as\\_senato](http://www.opb.org/news/article/america_pain_foundation_shuts_down_as_senato)



- Consistently minimizing the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain.<sup>311</sup>
- OxyContin is virtually non-addicting.<sup>312</sup>
- “Assur[ing] doctors – repeatedly and without evidence – that ‘fewer than one percent’ of patients who took OxyContin became addicted.”<sup>313</sup>



- OxyContin was addiction resistant and had “abuse-deterrent properties.”<sup>314</sup>
- Misrepresented the risk of addiction using misleading and inaccurate promotions of OxyContin that were unsupported by science.<sup>315</sup>

rs\_launch\_investigation\_of\_prescription\_narcotis/ (hereinafter “Ornstein, *American Pain Foundation*”).

<sup>311</sup> Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph*, Public Health Tragedy, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, “Van Zee, Promotion and Marketing”).

<sup>312</sup> Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

<sup>313</sup> *Id.*; see also “I got my life back,” OxyContin Promotional Video, 1998, <https://www.youtube.com/watch?v=Er78Dj5hyeI> (last accessed on March 8, 2018).

<sup>314</sup> *Id.*



- It was more difficult to extract the oxycodone from an OxyContin tablet for intravenous abuse.<sup>316</sup>
- OxyContin created fewer chances for addiction than immediate-release opioids.<sup>317</sup>
- OxyContin had fewer “peak and trough” effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.<sup>318</sup>
- Patients could abruptly stop opioid therapy without experiencing withdrawal symptoms, and patients who took OxyContin would not develop tolerance.<sup>319</sup>
- OxyContin did not cause a “buzz,” caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.<sup>320</sup>
- Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, “Indications of Possible Drug Abuse,” shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted

<sup>315</sup> Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), <https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf>.

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*

<sup>318</sup> *Id.*

<sup>319</sup> *Id.*

<sup>320</sup> *Id.*

1 through oral use. Thus, these misrepresentations wrongly reassured  
 2 doctors that as long as they do not observe those signs, they need not  
 3 worry that their patients are abusing or addicted to opioids.

- 4 ○ Purdue sponsored APF's *A Policymaker's Guide to Understanding*  
 5 *Pain & Its Management*, which inaccurately claimed that less than  
 6 1% of children prescribed opioids will become addicted. This  
 7 publication is still available online. This publication also asserted that  
 8 pain is undertreated due to "misconceptions about opioid addiction."  
 9 ○ Purdue sponsored APF's *Treatment Options: A Guide for People*  
 10 *Living with Pain* (2007), which asserted that addiction is rare and  
 11 limited to extreme cases of unauthorized dose escalations, obtaining  
 12 opioids from multiple sources, or theft.  
 13 ○ A Purdue-funded study with a Purdue co-author claimed that  
 14 "evidence that the risk of psychological dependence or addiction is  
 15 low in the absence of a history of substance abuse."<sup>321</sup> The study  
 16 relied only on the 1980 Porter-Jick letter to the editor concerning a  
 17 chart review of hospitalized patients, not patients taking Purdue's  
 18 long-acting, take-home opioid. Although the term "low" is not  
 19 defined, the overall presentation suggests the risk is so low as not to  
 20 be a worry.  
 21 ○ Purdue contracted with AGS to produce a CME promoting the 2009  
 22 guidelines for the *Pharmacological Management of Persistent Pain*  
 23 *in Older Persons*. These guidelines falsely claim that "the risks [of  
 24 addiction] are exceedingly low in older patients with no current or  
 25 past history of substance abuse." None of the references in the  
 26

27 <sup>321</sup> C. Peter N. Watson et al., Controlled-release oxycodone relieves neuropathic  
 28 pain: a randomized controlled trial I painful diabetic neuropathy, 105 *Pain* 71  
 (2003).

1 guidelines corroborates the claim that elderly patients are less likely  
 2 to become addicted to opioids and the claim is, in fact, untrue. Purdue  
 3 was aware of the AGS guidelines' content when it agreed to provide  
 4 this funding, and AGS drafted the guidelines with the expectation it  
 5 would seek drug company funding to promote them after their  
 6 completion.

- 7 ○ Purdue sponsored APF's *Exit Wounds* (2009), which counseled  
 8 veterans that "[l]ong experience with opioids shows that people who  
 9 are not predisposed to addiction are very unlikely to become addicted  
 10 to opioid pain medications." Although the term "very unlikely" is not  
 11 defined, the overall presentation suggests it is so low as not to be a  
 12 worry.
- 13 ○ Purdue sales representatives told prescribers that its drugs were  
 14 "steady state," the implication of which was that they did not produce  
 15 a rush or euphoric effect, and therefore were less addictive and less  
 16 likely to be abused.
- 17 ○ Purdue sales representatives told prescribers that Butrans has a lower  
 18 abuse potential than other drugs because it was essentially  
 19 tamperproof and, after a certain point, patients no longer experience a  
 20 "buzz" from increased dosage.
- 21 ○ Advertisements that Purdue sent to prescribers stated that OxyContin  
 22 ER was less likely to be favored by addicts, and, therefore, less likely  
 23 to be abused or diverted, or result in addiction.
- 24 ○ In discussions with prescribers, Purdue sales representatives omitted  
 25 discussion of addiction risks related to Purdue's drugs.
- 26 ● Janssen:
- 27 ○ **Myth:** Opioid medications are always addictive.
- 28

**Fact:** Many studies show that opioids are rarely addictive when used properly for the management of chronic pain.<sup>322</sup>

- **Myth:** Opioid doses have to get bigger over time because the body gets used to them.

**Fact:** Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.<sup>323</sup>

- “[Q]uestions of addiction,” “are often overestimated” because, “[a]ccording to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics.”<sup>324</sup>

#### *Other Opioid Analgesic Concerns*

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.<sup>15,16</sup> By the same token, patients report similar concerns about developing an addiction to opioid analgesics.<sup>17</sup> While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic therapy.<sup>18</sup>

- Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a “myth” that opioids are addictive, and asserts as fact that “[m]any studies show that opioids are rarely addictive when

<sup>322</sup> Finding Relief, Pain Management for Older Adults, (2009) (emphasis in original).

<sup>323</sup> Finding Relief, Pain Management for Older Adults, (2009) (emphasis in original).

<sup>324</sup> *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Dec. 11, 2017).

1           used properly for the management of chronic pain.” Although the  
2           term “rarely” is not defined, the overall presentation suggests the risk  
3           is so low as not to be a worry. The language also implies that as long  
4           as a prescription is given, opioid use is not a problem.

- 5           ○ Janssen contracted with AGS to produce a CME promoting the 2009  
6           guidelines for the *Pharmacological Management of Persistent Pain*  
7           *in Older Persons*. These guidelines falsely claim that “the risks [of  
8           addiction] are exceedingly low in older patients with no current or  
9           past history of substance abuse.” The study supporting this assertion  
10          does not analyze addiction rates by age and, as already noted,  
11          addiction remains a significant risk for elderly patients. Janssen was  
12          aware of the AGS guidelines’ content when it agreed to provide this  
13          funding, and AGS drafted the guidelines with the expectation it  
14          would seek drug company funding to promote them after their  
15          completion.
- 16          ○ Janssen provided grants to APF to distribute *Exit Wounds* (2009) to  
17          veterans, which taught that [l]ong experience with opioids shows that  
18          people who are not predisposed to addiction are very unlikely to  
19          become addicted to opioid pain medications.” Although the term  
20          “very unlikely” is not defined, the overall presentation suggests the  
21          risk is so low as not to be a worry.
- 22          ○ Janssen currently runs a website, [Prescriberresponsibly.com](http://Prescriberresponsibly.com) (last  
23          modified July 2, 2015), which claims that concerns about opioid  
24          addiction are “overstated.”
- 25          ○ A June 2009 Nucynta Training module warns Janssen’s sales force  
26          that physicians are reluctant to prescribe controlled substances like  
27          Nucynta, but this reluctance is unfounded because “the risks . . . are  
28          much smaller than commonly believed.”

- Janssen sales representatives told prescribers that its drugs were “steady state,” the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.
- Janssen sales representatives told prescribers that Nucynta and Nucynta ER were “not opioids,” implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen’s drugs. In truth, however, as set out in Nucynta’s FDA-mandated label, Nucynta “contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit.”
- Janssen’s sales representatives told prescribers that Nucynta’s unique properties eliminated the risk of addiction associated with the drug.
- In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen’s drugs.
- Cephalon:
  - Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which claims, among other things, that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.”
  - Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.
  - In discussions with prescribers, Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon’s drugs.



- 1 • Endo:
  - 2 ○ Opana ER was designed to be crush resistant
  - 3 ○ Opana ER was crush and abuse resistant and not addictive.<sup>325</sup>
  - 4 ○ “[T]he Reformulated Opana ER as ‘designed to be’ crush
  - 5 resistant.”<sup>326</sup>
  - 6 ○ “[P]atients treated with prolonged opioid medicines usually do not
  - 7 become addicted.”<sup>327</sup>
  - 8 ○ Endo trained its sales force in 2012 that use of long-acting opioids
  - 9 resulted in increased patient compliance, without any supporting
  - 10 evidence.
  - 11 ○ Endo’s advertisements for the 2012 reformulation of Opana ER
  - 12 claimed it was designed to be crush resistant, in a way that conveyed
  - 13 that it was less likely to be abused. This claim was false; the FDA
  - 14 warned in a May 10, 2013 letter that there was no evidence Endo’s
  - 15 design “would provide a reduction in oral, intranasal or intravenous
  - 16 abuse” and Endo’s “post-marketing data submitted are insufficient to
  - 17 support any conclusion about the overall or route-specific rates of
  - 18 abuse.” Further, Endo instructed its sales representatives to repeat
  - 19 this claim about “design,” with the intention of conveying Opana ER
  - 20 was less subject to abuse.
  - 21
  - 22
  - 23

24 <sup>325</sup> *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*,  
 Assurance No. 15-228, Assurance of Discontinuance Under Executive Law  
 25 Section 63, Subdivision 15, at 5 (Mar. 1, 2016),  
[https://ag.ny.gov/pdfs/Endo\\_AOD\\_030116-Fully\\_Executed.pdf](https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

26 <sup>326</sup> *Id.* at 6.

27 <sup>327</sup> *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*,  
 Assurance No. 15-228, Assurance of Discontinuance Under Executive Law  
 28 Section 63, Subdivision 15, at 5 (Mar. 1, 2016),  
[https://ag.ny.gov/pdfs/Endo\\_AOD\\_030116-Fully\\_Executed.pdf](https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

- 1           ○ Endo sponsored a website, painknowledge.com, through APF and  
2           NIPC, which claimed in 2009 that: “[p]eople who take opioids as  
3           prescribed usually do not become addicted.” Although the term  
4           “usually” is not defined, the overall presentation suggests the risk is  
5           so low as not to be a worry. The language also implies that as long as  
6           a prescription is given, opioid use will not become problematic. Endo  
7           continued to provide funding for this website through 2012, and  
8           closely tracked unique visitors to it.
- 9           ○ Endo sponsored a website, PainAction.com, which stated “Did you  
10          know? Most chronic pain patients do not become addicted to the  
11          opioid medications that are prescribed for them.”
- 12          ○ Endo sponsored CMEs published by APF’s NIPC, of which Endo  
13          was the sole funder, titled *Persistent Pain in the Older Adult and*  
14          *Persistent Pain in the Older Patient*. These CMEs claimed that  
15          opioids used by elderly patients present “possibly less potential for  
16          abuse than in younger patients[,]” which lacks evidentiary support  
17          and deceptively minimizes the risk of addiction for elderly patients.
- 18          ○ Endo distributed an education pamphlet with the Endo logo titled  
19          *Living with Someone with Chronic Pain*, which inaccurately  
20          minimized the risk of addiction: “Most health care providers who  
21          treat people with pain agree that most people do not develop an  
22          addiction problem.”
- 23          ○ Endo distributed a patient education pamphlet edited by key opinion  
24          leader Dr. Russell Portenoy titled *Understanding Your Pain: Taking*  
25          *Oral Opioid Analgesics*. It claimed that “[a]ddicts take opioids for  
26          other reasons [than pain relief], such as unbearable emotional  
27          28

1 problems.” This implies that pain patients prescribed opioids will not  
 2 become addicted, which is unsupported and untrue.

- 3 ○ Endo contracted with AGS to produce a CME promoting the 2009  
 4 guidelines for the *Pharmacological Management of Persistent Pain*  
 5 *in Older Persons*. These guidelines falsely claim that “the risks [of  
 6 addiction] are exceedingly low in older patients with no current or  
 7 past history of substance abuse.” None of the references in the  
 8 guidelines corroborates the claim that elderly patients are less likely  
 9 to become addicted to opioids, and there is no such evidence. Endo  
 10 was aware of the AGS guidelines’ content when it agreed to provide  
 11 this funding, and AGS drafted the guidelines with the expectation it  
 12 would seek drug company funding to promote them after their  
 13 completion.
- 14 ○ Endo sales representatives told prescribers that its drugs were “steady  
 15 state,” the implication of which was that they did not produce a rush  
 16 or euphoric effect, and therefore were less addictive and less likely to  
 17 be abused.
- 18 ○ Endo provided grants to APF to distribute *Exit Wounds* (2009) to  
 19 veterans, which taught that “[l]ong experience with opioids shows  
 20 that people who are not predisposed to addiction are very unlikely to  
 21 become addicted to opioid pain medications.” Although the term  
 22 “very unlikely” is not defined, the overall presentation suggests that  
 23 the risk is so low as not to be a worry.
- 24 ○ In discussions with prescribers, Endo sales representatives omitted  
 25 discussion of addiction risks related to Endo’s drugs.

26  
 27 515. The RICO Marketing Defendants misrepresented that opioids  
 28 improved function and quality of life:

1 • Purdue:

- 2 ○ “[W]e’ve discovered that the simplicity and convenience of twice-
- 3 daily dosing also enhances patient compliance with their doctor’s
- 4 instructions.”<sup>328</sup>

5

6 taking tablets every four to six hours. Moreover, we’ve discovered that

7 the simplicity and convenience of twice-daily dosing also enhances

8 [https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23\\_T23962617276&format=GNBF](https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23_T23962617276&format=GNBF)

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11 patient compliance with their doctor’s instructions.”

- 12 ○ Purdue ran a series of advertisements for OxyContin in 2012 in
- 13 medical journals titled “Pain vignettes,” which were case studies
- 14 featuring patients, each with pain conditions persisting over several
- 15 months, recommending OxyContin for each. One such patient,
- 16 “Paul,” is described to be a “54-year-old writer with osteoarthritis of
- 17 the hands,” and the vignettes imply that an OxyContin prescription
- 18 will help him work more effectively.
- 19 ○ Purdue sponsored APF’s *A Policymaker’s Guide to Understanding*
- 20 *Pain & Its Management*, which inaccurately claimed that “multiple
- 21 clinical studies” have shown that opioids are effective in improving
- 22 daily function, psychological health, and health-related quality of life
- 23 for chronic pain patients.” The sole reference for the functional
- 24 improvement claim noted the absence of long-term studies and
- 25 actually stated: “For functional outcomes, the other analgesics were
- 26
- 27

28 <sup>328</sup> Ryan, *Description of Hell*, <http://documents.latimes.com/oxycontin-press-release-1996/>

1 significantly more effective than were opioids.” *The Policymaker’s*  
 2 *Guide* is still available online.

- 3 ○ Purdue sponsored APF’s Treatment Options: A Guide for People  
 4 Living with Pain (2007), which counseled patients that opioids, when  
 5 used properly, “give [pain patients] a quality of life we deserve.”  
 6 APF distributed 17,200 copies in one year alone, according to its  
 7 2007 annual report, and the guide currently is available online.
- 8 ○ Purdue sponsored APF’s *Exit Wounds* (2009), which taught veterans  
 9 that opioid medications “increase your level of functioning.” *Exit*  
 10 *Wounds* also omits warnings of the risk of interactions between  
 11 opioids and benzodiazepines, which would increase fatality risk.  
 12 Benzodiazepines are frequently prescribed to veterans diagnosed with  
 13 post-traumatic stress disorder.
- 14 ○ Purdue sponsored the FSMB’s Responsible Opioid Prescribing  
 15 (2007), which taught that relief of pain itself improved patients’  
 16 function. Responsible Opioid Prescribing explicitly describes  
 17 functional improvement as the goal of a “long-term therapeutic  
 18 treatment course.” Purdue also spent over \$100,000 to support  
 19 distribution of the book.

- 20 ● Janssen:

- 21 ○ Misrepresented that patients experienced “[s]ignificantly reduced  
 22 nighttime awakenings.”<sup>329</sup>
- 23 ○ Misrepresented “[s]ignificant improvement in disability scores as  
 24 measured by the Oswestry Disability Questionnaire and Pain  
 25 Disability Index.”<sup>330</sup>

27 <sup>329</sup> NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to  
 28 Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

<sup>330</sup> *Id.*

- 1           ○ Misrepresented “[s]ignificant improvement in social functioning.”
- 2           ○ Misrepresented outcome claims that were misleading because they
- 3               lacked substantial support, evidence or clinical experience and
- 4               “impl[ied] that patients will experience improved social or physical
- 5               functioning or improved work productivity when using Duragesic,”
- 6               including: “1,360 loaves . . . and counting, [w]ork, uninterrupted,
- 7               [l]ife, uninterrupted, [g]ame, uninterrupted, [c]hronic pain relief that
- 8               supports functionality, [h]elps patients think less about their pain, and
- 9               [i]mprove[s] . . . physical and social functioning.”<sup>331</sup>
- 10          ○ Misrepresented that “[o]pioid analgesics, for example, have no true
- 11          ‘ceiling dose’ for analgesia and do not cause direct organ damage.”<sup>332</sup>

*Use of Opioid Analgesics in Pain Management*

Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true “ceiling dose” for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.<sup>8</sup>

- 18          ○ **Myth:** Opioids make it harder to function normally.
- 19               **Fact:** When used correctly for appropriate conditions, opioids may
- 20               make it easier for people to live normally.<sup>333</sup>
- 21          ○ Janssen sponsored a patient education guide titled *Finding Relief:*
- 22               *Pain Management for Older Adults* (2009), which its personnel
- 23               reviewed and approved and its sales force distributed. This guide
- 24

<sup>331</sup> *Id.* at 3 (internal quotations omitted).

<sup>332</sup> *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Dec. 11, 2017).

<sup>333</sup> *Finding Relief, Pain Management for Older Adults*, (2009) (emphasis in original).



1 features a man playing golf on the cover and lists examples of  
 2 expected functional improvement from opioids, like sleeping through  
 3 the night, returning to work, recreation, sex, walking, and climbing  
 4 stairs. The guide states as a “fact” that “opioids may make it easier  
 5 for people to live normally” (emphasis in the original). The myth/fact  
 6 structure implies authoritative backing for the claim that does not  
 7 exist. The targeting of older adults also ignored heightened opioid  
 8 risks in this population.

- 9 ○ Janssen sponsored, developed, and approved content of a website,  
 10 *Let’s Talk Pain* in 2009, acting in conjunction with the APF and  
 11 AAPM whose participation in Let’s Talk Pain Janssen financed and  
 12 orchestrated. This website featured an interview, which was edited by  
 13 Janssen personnel, claiming that opioids were what allowed a patient  
 14 to “continue to function,” inaccurately implying her experience  
 15 would be representative. This video is still available today on  
 16 youtube.com.
- 17 ○ Janssen provided grants to APF to distribute *Exit Wounds* to veterans,  
 18 which taught that opioid medications “increase your level of  
 19 functioning” (emphasis in the original). Exit Wounds also omits  
 20 warnings of the risk of interactions between opioids and  
 21 benzodiazepines, which would increase fatality risk. Benzodiazepines  
 22 are frequently prescribed to veterans diagnosed with post-traumatic  
 23 stress disorder.
- 24 • Cephalon:
- 25 ○ Cephalon sponsored the FSMB’s Responsible Opioid Prescribing  
 26 (2007), which taught that relief of pain itself improved patients’  
 27 function. Responsible Opioid Prescribing explicitly describes  
 28

functional improvement as the goal of a “long-term therapeutic treatment course.” Cephalon also spent \$150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

- Cephalon sponsored the American Pain Foundation’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly “give [pain patients] a quality of life we deserve.” The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online.
- Cephalon sponsored a CME written by Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon’s Actiq and Fentora improve patients’ quality of life and allow for more activities when taken in conjunction with long-acting opioids.
- Endo:
  - Opana ER “will benefit patients, physicians and payers.”<sup>334</sup>

"Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."

<sup>334</sup> *FDA Approves Endo Pharmaceuticals’ Crush-Resistant Opana ER*, December 12, 2011, <https://www.biospace.com/article/releases/fda-approves-endo-pharmaceuticals-crush-resistant-opana-er/>.

- 1           ○ “Endo distributed a pamphlet in New York and posted on its public  
2           website, [www.opana.com](http://www.opana.com), photographs of purported Opana ER  
3           patients that implied that patients can achieve higher function with  
4           Opana ER.”<sup>335</sup>
- 5           ○ Endo sponsored a website, [painknowledge.com](http://painknowledge.com), through APF and  
6           NIPC, which claimed in 2009 that with opioids, “your level of  
7           function should improve; you may find you are now able to  
8           participate in activities of daily living, such as work and hobbies, that  
9           you were not able to enjoy when your pain was worse.” Endo  
10          continued to provide funding for this website through 2012, and  
11          closely tracked unique visitors to it.
- 12          ○ A CME sponsored by Endo, titled *Persistent Pain in the Older*  
13          *Patient*, taught that chronic opioid therapy has been “shown to reduce  
14          pain and improve depressive symptoms and cognitive functioning.”
- 15          ○ Endo distributed handouts to prescribers that claimed that use of  
16          Opana ER to treat chronic pain would allow patients to perform work  
17          as a chef. This flyer also emphasized Opana ER’s indication without  
18          including equally prominent disclosure of the “moderate to severe  
19          pain” qualification.
- 20          ○ Endo’s sales force distributed FSMB’s *Responsible Opioid*  
21          *Prescribing* (2007). This book taught that relief of pain itself  
22          improved patients’ function. *Responsible Opioid Prescribing*  
23          explicitly describes functional improvement as the goal of a “long-  
24          term therapeutic treatment course.”
- 25          ○ Endo provided grants to APF to distribute *Exit Wounds* to veterans,  
26          which taught that opioid medications “increase your level of  
27

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28          <sup>335</sup> *Id.* at 8.

functioning” (emphasis in the original). Exit Wounds also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

516. The RICO Marketing Defendants misrepresented that addiction risks can be avoided or managed through screening tools and prescription guidelines:

- Purdue:

- Purdue’s unbranded website, In the Face of Pain (inthefaceofpain.com) states that policies that “restrict[] access to patients with pain who also have a history of substance abuse” and “requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe” are “at odds with” best medical practices.<sup>336</sup>
- Purdue sponsored a 2012 CME program taught by a KOL titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.
- Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication taught prescribers that screening tools, urine tests, and

<sup>336</sup> See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment, Purdue Pharma L.P. (Resources verified Mar. 2012), [www.inthefaceofpain.com/content/uploads/2011/12/factsheet\\_ProtectingAccess.pdf](http://www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf).

1 patient agreements have the effect of preventing “overuse of  
2 prescriptions” and “overdose deaths.”

- 3 ○ Purdue sales representatives told prescribers that screening tools can  
4 be used to select patients appropriate for opioid therapy and to  
5 manage the risks of addiction.

- 6 • Cephalon:

- 7 ○ Cephalon sponsored APF’s *Treatment Options: A Guide for People*  
8 *Living with Pain* (2007), which taught patients that “opioid  
9 agreements” between doctors and patients can “ensure that you take  
10 the opioid as prescribed.”

- 11 • Endo:

- 12 ○ Endo paid for a 2007 supplement<sup>337</sup> available for continuing  
13 education credit in the Journal of Family Practice and written by a  
14 doctor who later became a member of Endo’s speakers bureau. This  
15 publication, titled *Pain Management Dilemmas in Primary Care:*  
16 *Use of Opioids*, recommended screening patients using tools like the  
17 Opioid Risk Tool or the Screener and Opioid Assessment for Patients  
18 with Pain, and advised that patients at high risk of addiction could  
19 safely (e.g., without becoming addicted) receive chronic opioid  
20 therapy using a “maximally structured approach” involving  
21 toxicology screens and pill counts.

22 517. The RICO Marketing Defendants misrepresented that signs of opioid  
23 addiction were not addiction, withdrawal could be simply managed, and promoted  
24 the concept of pseudoaddiction:

- 25 • Purdue:

26  
27 <sup>337</sup> The Medical Journal, The Lancet found that all of the supplement papers it  
28 received failed peer-review. Editorial, “*The Perils of Journal and Supplement*  
*Publishing*,” 375 The Lancet 9712 (347) 2010.

- 1           ○ Purdue published a prescriber and law enforcement education  
2           pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which  
3           described pseudoaddiction as a concept that “emerged in the  
4           literature to describe the inaccurate interpretation of [drug-seeking  
5           behaviors] in patients who have pain that has not been effectively  
6           treated.”
- 7           ○ Purdue distributed to physicians, at least as of November 2006 and  
8           posted on its unbranded website, Partners Against Pain, a pamphlet  
9           copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*.  
10          This pamphlet included a list of conduct including “illicit drug use  
11          and deception” it defined as indicative of pseudoaddiction or  
12          untreated pain. It also states: “Pseudoaddiction is a term which has  
13          been used to describe patient behaviors that may occur when pain is  
14          undertreated. . . . Even such behaviors as illicit drug use and  
15          deception can occur in the patient’s efforts to obtain relief.  
16          Pseudoaddiction can be distinguished from true addiction in that the  
17          behaviors resolve when the pain is effectively treated.”
- 18          ○ Purdue sponsored FSMB’s *Responsible Opioid Prescribing* (2007),  
19          which taught that behaviors such as “requesting drugs by name,  
20          “demanding or manipulative behavior,” seeing more than one doctor  
21          to obtain opioids, and hoarding, are all signs of pseudoaddiction.  
22          Purdue also spent over \$100,000 to support distribution of the book.
- 23          ○ Purdue sponsored APF’s *A Policymaker’s Guide to Understanding*  
24          *Pain & Its Management*, which states: “Pseudo-addiction describes  
25          patient behaviors that may occur when pain is undertreated. . . .  
26          Pseudo-addiction can be distinguished from true addiction in that this  
27          behavior ceases when pain is effectively treated.”  
28



- *A Policymaker's Guide to Understanding Pain & Its Management* also taught that “Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation,” but did not disclose the significant hardships that often accompany cessation of use.
  - Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed.
  - Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans’ low potency and its extended release mechanism.
- Janssen:
  - Janssen’s website, Let’s Talk Pain, stated from 2009 through 2011 that “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated” and “[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
  - A Janssen PowerPoint presentation used for training its sales representatives titled “*Selling Nucynta ER*” indicates that the “low incidence of withdrawal symptoms” is a “core message” for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate

1 of withdrawal symptoms, Janssen relied upon a study that only began  
 2 tracking withdrawal symptoms in patients two to four days after  
 3 discontinuing opioid use, when Janssen knew or should have known  
 4 that these symptoms peak earlier than that for most patients. Relying  
 5 on data after that initial window painted a misleading picture of the  
 6 likelihood and severity of withdrawal associated with chronic opioid  
 7 therapy. Janssen also knew or should have known that the patients  
 8 involved in the study were not on the drug long enough to develop  
 9 rates of withdrawal symptoms comparable to rates of withdrawal  
 10 suffered by patients who use opioids for chronic pain—the use for  
 11 which Janssen promoted Nucynta ER.

- 12 ○ Janssen sales representatives told prescribers that patients on  
 13 Janssen’s drugs were less susceptible to withdrawal than those on  
 14 other opioids.

- 15 • Cephalon:

- 16 ○ Cephalon sponsored FSMB’s Responsible Opioid Prescribing (2007),  
 17 which taught that behaviors such as “requesting drugs by name,”  
 18 “demanding or manipulative behavior,” seeing more than one doctor  
 19 to obtain opioids, and hoarding are all signs of pseudoaddiction.  
 20 Cephalon also spent \$150,000 to purchase copies of the book in bulk  
 21 and distributed it through its pain sales force to 10,000 prescribers  
 22 and 5,000 pharmacists.

- 23 • Endo:

- 24 ○ Endo distributed copies of a book by KOL Dr. Lynn Webster entitled  
 25 *Avoiding Opioid Abuse While Managing Pain* (2007). Endo’s internal  
 26 planning documents describe the purpose of distributing this book as  
 27 to “[i]ncrease the breadth and depth of the Opana ER prescriber  
 28

base.” The book claims that when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose in most cases . . . should be the clinician’s first response.”

- Endo spent \$246,620 to buy copies of FSMB’s *Responsible Opioid Prescribing* (2007), which was distributed by Endo’s sales force. This book asserted that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of “pseudoaddiction.”
- A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.
- Endo misrepresented that “symptoms of withdrawal do not indicate addiction.”<sup>338</sup>
- “Endo also trained its sales representatives to distinguish addiction from ‘pseudoaddiction.’”<sup>339</sup>

518. The RICO Defendants misrepresented that opioids were safe for the long-term treatment of chronic, non-acute, and non-cancer pain:

- Purdue:

- “[W]e do not want to niche OxyContin just for cancer pain.”<sup>340</sup>

three tablet strengths were passed around. OxyContin will be indicated for the relief of pain with the convenience of q12h dosing. OxyContin’s primary market positioning will be for cancer pain and the secondary market will be for non-malignant pain (musculoskeletal, injury and trauma). It was reinforced that we do not want to niche OxyContin just for cancer pain. OxyContin will be positioned into Step 2 of the

<sup>338</sup> *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 7 (Mar. 1, 2016), [https://ag.ny.gov/pdfs/Endo\\_AOD\\_030116-Fully\\_Executed.pdf](https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

<sup>339</sup> *Id.*

<sup>340</sup> Ryan, *Description of Hell*, <http://documents.latimes.com/oxycontin-launch-1995/> (emphasis in the L.A. Times document).

- OxyContin was safe and non-addictive when using extended release formulations, and appropriate for use in non-cancer patients.<sup>341</sup>
- OxyContin should be prescribed not merely for severe short-term pain associated with surgery or cancer, but also for less acute, longer-lasting pain like arthritis, back pain, sports injuries, fibromyalgia with almost limitless treatment potential.<sup>342</sup>
- Janssen:
  - Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.”<sup>343</sup>
  - Duragesic was “not just for end stage cancer anymore” when the FDA only approved Duragesic for “the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means.”<sup>344</sup>
  - Misrepresented that “Duragesic can be used for any type of pain management” despite the fact that the FDA approved warning stated that “BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS

<sup>341</sup> Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), [http://www.opb.org/news/article/america\\_pain\\_foundation\\_shuts\\_down\\_as\\_senators\\_launch\\_investigation\\_of\\_prescription\\_narcotics/](http://www.opb.org/news/article/america_pain_foundation_shuts_down_as_senators_launch_investigation_of_prescription_narcotics/) (hereinafter “Ornstein, *American Pain Foundation*”).

<sup>342</sup> Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

<sup>343</sup> NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

<sup>344</sup> *Id.*

1 CONTRAINDICATED: In the management of acute or post-  
 2 operative pain, including use in outpatient surgeries . . . .”<sup>345</sup>

3 ○ Misrepresented “numerous claims for the efficacy and safety of  
 4 Duragesic,” but failed to “present[] any risk information concerning  
 5 the boxed warnings, contraindications, warnings, or side effects  
 6 associated with Duragesic’s use . . . [and] . . . fail[ed] to address  
 7 important risks and restrictions associated with Duragesic  
 8 therapy.”<sup>346</sup>

9 ○ Misrepresented “[d]emonstrated effectiveness in chronic back pain  
 10 with additional patient benefits, . . . 86% of patients experienced  
 11 overall benefit in a clinical study based on: pain control, disability in  
 12 ADLs, quality of sleep.”<sup>347</sup>

13 • Cephalon:

14 ○ “[P]romoting [Actiq] for non-cancer patients to use for such maladies  
 15 as migraines, sickle-cell pain crises, injuries, and in anticipation of  
 16 changing wound dressings or radiation therapy.”<sup>348</sup>

17 ○ “[P]romot[ing] Actiq for use in patients who were not yet opioid  
 18 tolerant, and for whom it could have life-threatening results.”<sup>349</sup>

19 ○ In 2011, Cephalon wrote an article titled “2011 Special Report: An  
 20 Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl  
 21 Buccal Tablet (FENTORA®) AND Oral Transmucosal Fentanyl  
 22 Citrate (Actiq®), published in Pain Medicine News. Plaintiffs are  
 23

24 <sup>345</sup> *Id.*

25 <sup>346</sup> *Id.*

26 <sup>347</sup> *Id.* at 2-3.

27 <sup>348</sup> Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon  
 To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008),  
<https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

28 <sup>349</sup> *Id.*

1 informed and believe that Cephalon misrepresented that its drugs  
 2 were “shown to be effective in treatment of [break through pain]  
 3 associated with multiple causes of pain,” not just cancer.

4 519. The RICO Defendants also misrepresented that opioids were safer  
 5 that non-opioid analgesics because there is no ceiling dose for opioid treatment.

6 • Purdue:

- 7 ○ Purdue’s In the Face of Pain website, along with initiatives of APF,  
 8 promoted the notion that if a patient’s doctor does not prescribe them  
 9 what—in their view—is a sufficient dose of opioids, they should find  
 10 another doctor who will. In so doing, Purdue exerted undue, unfair,  
 11 and improper influence over prescribers who face pressure to accede  
 12 to the resulting demands.
- 13 ○ Purdue sponsored APF’s *A Policymaker’s Guide to Understanding*  
 14 *Pain & Its Management*, which taught that dose escalations are  
 15 “sometimes necessary,” even indefinitely high ones, which suggested  
 16 that high dose opioids are safe and appropriate and did not disclose  
 17 the risks from high dose opioids. This publication is still available  
 18 online.
- 19 ○ Purdue sponsored APF’s *Treatment Options: A Guide for People*  
 20 *Living with Pain* (2007), which taught patients that opioids have “no  
 21 ceiling dose” and are therefore the most appropriate treatment for  
 22 severe pain. The guide also claimed that some patients “need” a  
 23 larger dose of the drug, regardless of the dose currently prescribed.  
 24 This language fails to disclose heightened risks at elevated doses.
- 25 ○ *Treatment Options*, also taught that opioids differ from NSAIDs in  
 26 that they have “no ceiling dose” and are therefore the most  
 27 appropriate treatment for severe pain. *Treatment Options* continued,  
 28



1 warning that risks of NSAIDs increase if “taken for more than a  
 2 period of months,” with no corresponding warning about opioids.  
 3 The publication attributed 10,000 to 20,000 deaths annually to  
 4 NSAID overdose.

- 5 ○ Purdue sponsored a CME issued by the American Medical  
 6 Association in 2003, 2007, 2010, and 2013. The CME, *Overview of*  
 7 *Management Options*, was edited by KOL Dr. Russell Portenoy,  
 8 among others, and taught that other drugs, but not opioids, are unsafe  
 9 at high doses. The 2013 version is still available for CME credit.
- 10 ○ *Overview of Management Options* also taught NSAIDs and other  
 11 drugs, but not opioids, are unsafe at high doses.
- 12 ○ Purdue sponsored APF’s *Exit Wounds* (2009), which omits warnings  
 13 of the risk of interactions between opioids and benzodiazepines,  
 14 which would increase fatality risk. *Exit Wounds* also contained a  
 15 lengthy discussion of the dangers of using alcohol to treat chronic  
 16 pain but did not disclose dangers of mixing
- 17 ○ Purdue sales representatives told prescribers that opioids were just as  
 18 effective for treating patients long-term and omitted any discussion  
 19 that increased tolerance would require increasing, and increasingly  
 20 dangerous, doses.
- 21 ○ Purdue sales representatives told prescribers that NSAIDs were more  
 22 toxic than opioids.

- 23 • Janssen:

- 24 ○ Janssen sponsored a patient education guide entitled *Finding Relief:*  
 25 *Pain Management for Older Adults* (2009), which its personnel  
 26 reviewed and approved and its sales force distributed. This guide  
 27 listed dose limitations as “disadvantages” of other pain medicines but  
 28

omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a “myth” that “opioid doses have to be bigger over time.”

- *Finding Relief: Pain Management for Older Adults* also described the advantages and disadvantages of NSAIDs on one page, and the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are “upset stomach or sleepiness,” which the brochure claims will go away, and constipation.
- Janssen sponsored APF’s *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen’s label for Duragesic, however, states that use with benzodiazepines “may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. Exit Wounds also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.
- Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is an opioid and has the same effects as other opioids.

- Cephalon:

- Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.
- *Treatment Options*, also taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. *Treatment Options* continued, warning that risks of NSAIDs increase if "taken more than a period of months." With no corresponding warning about opioids. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose.
- Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.
- Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.
- Cephalon sales representatives told prescribers that NSAIDs were more toxic than opioids.
- "[P]romot[ing] Actiq for use in patients who were not yet opioid tolerant, and for whom it could have life-threatening results."<sup>350</sup>
- Endo:
  - Endo sponsored a website, [painknowledge.com](http://painknowledge.com), through APF and NIPC, which claimed in 2009 that opioids may be increased until

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<sup>350</sup> *Id.*

1 “you are on the right dose of medication for your pain,” and once that  
 2 occurs, further dose increases would not occur. Endo funded the site,  
 3 which was a part of Endo’s marketing plan, and tracked visitors to it.

- 4 ○ Through painknowledge.com Endo distributed a flyer called “Pain:  
 5 Opioid Therapy.” This publication included a list of adverse effects  
 6 from opioids that omitted significant adverse effects like  
 7 hyperalgesia, immune and hormone dysfunction, cognitive  
 8 impairment, tolerance, dependence, addiction, and death. Endo  
 9 continued to provide funding for this website through 2012, and  
 10 closely tracked unique visitors to it.
- 11 ○ Endo provided grants to APF to distribute Exit Wounds (2009),  
 12 which omitted warnings of the risk of interactions between opioids  
 13 and benzodiazepines, which would increase fatality risk. Exit  
 14 Wounds also contained a lengthy discussion of the dangers of using  
 15 alcohol to treat chronic pain but did not disclose dangers of mixing  
 16 alcohol and opioids.
- 17 ○ Endo sales representatives told prescribers that NSAIDs were more  
 18 toxic than opioids.
- 19 ○ Endo distributed a patient education pamphlet edited by KOL Dr.  
 20 Russell Portenoy titled *Understanding Your Pain: Taking Oral*  
 21 *Opioid Analgesics*. In Q&A format, it asked: “If I take the opioid  
 22 now, will it work later when I really need it?” The response was:  
 23 “The dose can be increased . . . . You won’t ‘run out’ of pain relief.”
- 24 ○ Endo distributed a “case study” to prescribers titled *Case Challenges*  
 25 *in Pain Management: Opioid Therapy for Chronic Pain*. The study  
 26 cites an example, meant to be representative, of a patient “with a  
 27 massive upper gastrointestinal bleed believed to be related to his  
 28

1           protracted use of NSAIDs” (over eight years), and recommends  
2           treating with opioids instead.

3           520. These misrepresentations, and the legion of other representations  
4 made by the RICO Defendants and members of Opioid Marketing Enterprise all  
5 furthered the common purpose and fraudulent scheme of the Opioid Marketing  
6 Enterprise. But they were demonstrably false, as confirmed by investigations and  
7 enforcement actions against the RICO Marketing Defendants.

8           521. In May 2007, Purdue and three of its executives pled guilty to federal  
9 charges of misbranding OxyContin in what the company acknowledged was an  
10 attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay  
11 \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of  
12 OxyContin was misleading and inaccurate, misrepresented the risk of addiction  
13 and was unsupported by science. The Order adopting the guilty pleas provide:

14  
15                       effects than immediate-release opioids resulting in less  
16                       euphoria and less potential for abuse than short-acting  
                          opioids;

17           d. Told certain health care providers that patients could stop  
18           therapy abruptly without experiencing withdrawal  
19           symptoms and that patients who took OxyContin would not  
                      develop tolerance to the drug; and

20           e. Told certain health care providers that OxyContin did not  
21           cause a “buzz” or euphoria, caused less euphoria, had less  
22           addiction potential, had less abuse potential, was less likely  
                      to be diverted than immediate-release opioids, and could be  
                      used to “weed out” addicts and drug seekers.

23           (Information ¶ 19.) Purdue has agreed that these facts are true, and the individual  
24           defendants, while they do not agree that they had knowledge of these things, have  
25           agreed that the court may accept these facts in support of their guilty pleas. (Agreed  
26           Statement of Facts ¶ 46.)

27           522. Additionally, Michael Friedman (“Friedman”), the company’s  
28           president, pled guilty to a misbranding charge and agreed to pay \$19 million in

1 fines; Howard R. Udell (“Udell”), Purdue’s top lawyer, also pled guilty and  
 2 agreed to pay \$8 million in fines; and Paul D. Goldenheim (“Goldenheim”), its  
 3 former medical director, pled guilty as well and agreed to pay \$7.5 million in  
 4 fines.<sup>351</sup>

5 523. In a statement announcing the guilty plea, John Brownlee  
 6 (“Brownlee”), the U.S. Attorney for the Western District of Virginia, stated:

7 Purdue claimed it had created the miracle drug – a low risk drug that  
 8 could provide long acting pain relief but was less addictive and less  
 9 subject to abuse. Purdue’s marketing campaign worked, and sales for  
 10 OxyContin skyrocketed – making billions for Purdue and millions for  
 11 its top executives.

12 But OxyContin offered no miracles to those suffering in pain.  
 13 Purdue’s claims that OxyContin was less addictive and less subject to  
 14 abuse and diversion were false – and Purdue knew its claims were  
 15 false. The result of their misrepresentations and crimes sparked one of  
 16 our nation’s greatest prescription drug failures. . . . OxyContin was the  
 17 child of marketers and bottom line financial decision making.<sup>352</sup>

18 524. Brownlee characterized Purdue’s criminal activity as follows:

19 First, Purdue trained its sales representatives to falsely inform  
 20 health care providers that it was more difficult to extract the  
 21 oxycodone from an OxyContin tablet for the purpose of intravenous  
 22 abuse. Purdue ordered this training even though its own study showed  
 23 that a drug abuser could extract approximately 68% of the oxycodone  
 24 from a single 10 mg OxyContin tablet by simply crushing the tablet,  
 25 stirring it in water, and drawing the solution through cotton into a  
 26 syringe.

27 Second, Purdue falsely instructed its sales representatives to  
 28 inform health care providers that OxyContin could create fewer  
 chances for addiction than immediate-release opioids.

Third, Purdue sponsored training that falsely taught Purdue  
 sales supervisors that OxyContin had fewer “peak and trough” blood  
 level effects than immediate-release opioids resulting in less euphoria  
 and less potential for abuse than short-acting opioids.

Fourth, Purdue falsely told certain health care providers that  
 patients could stop therapy abruptly without experiencing withdrawal

<sup>351</sup> *Id.*

<sup>352</sup> Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), <https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf>.



1 symptoms and that patients who took OxyContin would not develop  
2 tolerance to the drug.

3 And fifth, Purdue falsely told health care providers that  
4 OxyContin did not cause a “buzz” or euphoria, caused less euphoria,  
5 had less addiction potential, had less abuse potential, was less likely to  
6 be diverted than immediate-release opioids, and could be used to  
7 “weed out” addicts and drug seekers.<sup>353</sup>

8 525. Purdue pled guilty to illegally misbranding OxyContin in an effort to  
9 mislead and defraud physicians and consumers, while Friedman, Udell and  
10 Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin for  
11 introducing misbranded drugs into interstate commerce in violation of 21 U.S.C.  
12 §§ 331(a), 333(a)(1)-(2) and 352(a).

13 526. Similarly, Endo’s marketing of Purdue was criticized and punished  
14 by the FDA and New York Attorney General.

15 527. On February 18, 2017, the State of New York announced a  
16 settlement with Endo requiring it “to cease all misrepresentations regarding the  
17 properties of Opana ER [and] to describe accurately the risk of addiction to Opana  
18 ER.”<sup>354</sup> In the Assurance of Discontinuance that effectuated the settlement, the  
19 State of New York stated that Endo knew about the risks arising from the  
20 reformulated Opana ER even before it received FDA approval. Among other  
21 things, the investigation concluded that:

- 22 • Endo improperly marketed Opana ER as designed to be crush resistant,  
23 when Endo’s own studies dating from 2009 and 2010 showed that the pill  
24 could be crushed and ground;

25 <sup>353</sup> *Id.*

26 <sup>354</sup> Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman  
27 Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals  
28 Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016),  
<https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals> (last accessed on March 9, 2018).

- 1 • Endo improperly instructed its sales representatives to diminish and distort
- 2 the risks associated with Opana ER, including the serious danger of
- 3 addiction; and
- 4 • Endo made unsupported claims comparing Opana ER to other opioids and
- 5 failed to disclose accurate information regarding studies addressing the
- 6 negative effects of Opana ER.<sup>355</sup>

7 528. The 2017 settlement also identified and discussed a February 2013  
 8 communication from a consultant hired by Endo to the company, in which the  
 9 consultant concluded that “[t]he initial data presented do not necessarily establish  
 10 that the reformulated Opana ER is tamper resistant.” The same consultant also  
 11 reported that the distribution of the reformulated Opana ER had already led to  
 12 higher levels of abuse of the drug via injection.<sup>356</sup>

13 529. The Office of the Attorney General of New York also revealed that  
 14 the “managed care dossier” Endo provided to formulary committees of healthcare  
 15 plans and pharmacy benefit managers misrepresented the studies that had been  
 16 conducted on Opana ER. According to Endo’s vice president for  
 17 pharmacovigilance and risk management, the dossier was presented as a complete  
 18 compendium of all research on the drug. However, it omitted certain studies:  
 19 Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed  
 20 that reformulated Opana ER could be ground and chewed.

21 530. The settlement also detailed Endo’s false and misleading  
 22 representations about the non-addictiveness of opioids and Opana. For example,  
 23 until April 2012, Endo’s website for the drug, [www.opana.com](http://www.opana.com), contained the  
 24 following representation: “Most healthcare providers who treat patients with pain  
 25 agree that patients treated with prolonged opioid medicines usually do not become  
 26

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27 <sup>355</sup> *Id.*

28 <sup>356</sup> *Id.* at 6.

1 addicted.”<sup>357</sup> However, Endo neither conducted nor possessed a survey  
2 demonstrating that most healthcare providers who treat patients with pain agree  
3 with that representation.

4 531. The Office of the Attorney General of New York also disclosed the  
5 following facts that it determined to violate Opana’s obligations to truthfully  
6 market its products:

7 a. Training materials provided by Endo to sales  
8 representatives stated: “Symptoms of withdrawal do not  
9 indicate addiction.”<sup>358</sup> This representation is inconsistent with  
10 the diagnosis of opioid-use disorder as provided in the  
11 Diagnostic and Statistical Manual of Mental Disorders by the  
12 American Psychiatric Association (Fifth Edition).

13 b. Endo trained its sales representatives to falsely  
14 distinguish addiction from “pseudoaddiction,” which it defined  
15 as a condition in which patients exhibit drug-seeking behavior  
16 that resembles but is not the same as addiction. Endo’s vice  
17 president for pharmacovigilance and risk management testified  
18 that he was not aware of any research validating the concept of  
19 pseudoaddiction.

20 532. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of  
21 Opana ER after determining that the risks associated with its abuse outweighed  
22 the benefits. According to Dr. Janet Woodcock, director of the FDA’s Center for  
23 Drug Evaluation and Research, the risks include “several serious problems,”  
24 including “outbreaks of HIV and Hepatitis C from sharing the drug after it was  
25  
26  
27

28 <sup>357</sup> *Id.*

<sup>358</sup> *Id.* at 7.

1 extracted by abusers” and “”a serious disease outbreak.”<sup>359</sup> If Endo did not  
 2 comply, the FDA stated that it “intends to take steps to formally require its  
 3 removal by withdrawing approval.”<sup>360</sup>

4 533. Like Purdue and Endo, Janssen was the subject of an FDA  
 5 enforcement action that identified its marketing statements as misrepresentations.  
 6 For example:

7 534. On February 15, 2000, the FDA sent Janssen a letter concerning the  
 8 alleged dissemination of “homemade” promotional pieces that promoted  
 9 Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a  
 10 subsequent letter, dated March 30, 2000, the FDA explained that the “homemade”  
 11 promotional pieces were “false or misleading because they contain  
 12 misrepresentations of safety information, broaden Duragesic’s indication, contain  
 13 unsubstantiated claims, and lack fair balance.”<sup>361</sup>

14 535. The March 30, 2000 letter identified specific violations, including  
 15 misrepresentations that Duragesic had a low potential for abuse:

16 You present the claim, “Low abuse potential!” This claim suggests  
 17 that Duragesic has less potential for abuse than other currently  
 18 available opioids. However, this claim has not been demonstrated by  
 19 substantial evidence. Furthermore, this claim is contradictory to  
 20 information in the approved product labeling (PI) that states,  
 “Fentanyl is a Schedule II controlled substance and can produce drug  
 dependence similar to that produced by morphine.” Therefore, this  
 claim is false or misleading.<sup>362</sup>

21 536. The March 30, 2000 letter also stated that the promotional materials  
 22 represented that Duragesic was “more useful in a broader range of conditions or  
 23

24  
 25 <sup>359</sup> *FDA requests removal of Opana ER for risks related to abuse*, June 8, 2017,  
[https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.ht](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)  
 26 [m](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm).

27 <sup>360</sup> *Id.*

28 <sup>361</sup> NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to  
 Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

<sup>362</sup> *Id.*

1 patients than has been demonstrated by substantial evidence.”<sup>363</sup> Specifically, the  
 2 FDA stated that Janssen was marketing Duragesic for indications other than the  
 3 treatment of chronic pain that cannot otherwise be managed, for which it was  
 4 approved:

5 You present the claim, “It’s not just for end stage cancer anymore!”  
 6 This claim suggests that Duragesic can be used for any type of pain  
 7 management. However, the PI for Duragesic states, “Duragesic  
 8 (fentanyl transdermal system) is indicated in the management of  
 9 chronic pain in patients who require continuous opioid analgesia for  
 10 pain that cannot be managed by lesser means . . . .” Therefore, the  
 11 suggestion that Duragesic can be used for any type of pain  
 12 management promotes Duragesic[] for a much broader use than is  
 13 recommended in the PI, and thus, is misleading. In addition, the  
 14 suggestion that Duragesic can be used to treat any kind of pain is  
 15 contradictory to the boxed warning in the PI. Specifically, the PI  
 16 states,

17 **BECAUSE SERIOUS OR LIFE-THREATENING**  
 18 **HYPOVENTILATION COULD OCCUR, DURAGESIC®**  
 19 **(FENTANYL TRANSDERMAL SYSTEM) IS**  
 20 **CONTRAINDICATED:**

21 In the management of acute or post-operative pain, including use in  
 22 outpatient surgeries . . . .<sup>364</sup>

23 537. The March 30, 2000 letter also stated Janssen failed to adequately  
 24 present “contraindications, warnings, precautions, and side effects with a  
 25 prominence and readability reasonably comparable to the presentation of  
 26 information relating to the effectiveness of the product.”<sup>365</sup>

27 538. On February 15, 2000, the FDA sent Janssen a letter concerning the  
 28 alleged dissemination of “homemade” promotional pieces that promoted  
 Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a  
 subsequent letter, dated March 30, 2000, the FDA explained that the “homemade”  
 promotional pieces were “false or misleading because they contain

<sup>363</sup> *Id.*

<sup>364</sup> *Id.* at 2-3.

<sup>365</sup> *Id.* at 3 (emphasis in original).

1 misrepresentations of safety information, broaden Duragesic's indication, contain  
2 unsubstantiated claims, and lack fair balance.”<sup>366</sup>

3 539. The March 30, 2000 letter identified specific violations, including  
4 misrepresentations that Duragesic had a low potential for abuse:

5 You present the claim, “Low abuse potential!” This claim suggests  
6 that Duragesic has less potential for abuse than other currently  
7 available opioids. However, this claim has not been demonstrated by  
8 substantial evidence. Furthermore, this claim is contradictory to  
9 information in the approved product labeling (PI) that states,  
10 “Fentanyl is a Schedule II controlled substance and can produce drug  
11 dependence similar to that produced by morphine.” Therefore, this  
12 claim is false or misleading.<sup>367</sup>

13 540. The March 30, 2000 letter also stated that the promotional materials  
14 represented that Duragesic was “more useful in a broader range of conditions or  
15 patients than has been demonstrated by substantial evidence.”<sup>368</sup> Specifically, the  
16 FDA stated that Janssen was marketing Duragesic for indications other than the  
17 treatment of chronic pain that cannot otherwise be managed, for which it was  
18 approved:

19 You present the claim, “It’s not just for end stage cancer anymore!”  
20 This claim suggests that Duragesic can be used for any type of pain  
21 management. However, the PI for Duragesic states, “Duragesic  
22 (fentanyl transdermal system) is indicated in the management of  
23 chronic pain in patients who require continuous opioid analgesia for  
24 pain that cannot be managed by lesser means . . . .” Therefore, the  
25 suggestion that Duragesic can be used for any type of pain  
26 management promotes Duragesic[] for a much broader use than is  
27 recommended in the PI, and thus, is misleading. In addition, the  
28 suggestion that Duragesic can be used to treat any kind of pain is  
contradictory to the boxed warning in the PI. Specifically, the PI  
states,

BECAUSE SERIOUS OR LIFE-THREATENING  
HYPOVENTILATION COULD OCCUR, DURAGESIC®  
(FENTANYL TRANSDERMAL SYSTEM) IS  
CONTRAINDICATED:

<sup>366</sup> NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to  
Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

<sup>367</sup> *Id.*

<sup>368</sup> *Id.*



1 In the management of acute or post-operative pain, including use in  
outpatient surgeries . . . .<sup>369</sup>

2 541. The March 30, 2000 letter also stated Janssen failed to adequately  
3 present “contraindications, warnings, precautions, and side effects with a  
4 prominence and readability reasonably comparable to the presentation of  
5 information relating to the effectiveness of the product”:

6 Although this piece contains numerous claims for the efficacy and  
7 safety of Duragesic, you have not presented any risk information  
8 concerning the boxed warnings, contraindications, warnings,  
9 precautions, or side effects associated with Duragesic’s use . . . .  
Therefore, this promotional piece is lacking in fair balance, or  
otherwise misleading, because it fails to address important risks and  
restrictions associated with Duragesic therapy.<sup>370</sup>

10 542. On September 2, 2004, the U.S. Department of Health and Human  
11 Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to  
12 “false or misleading claims about the abuse potential and other risks of the drug,  
13 and . . . unsubstantiated effectiveness claims for Duragesic,” including,  
14 specifically, “suggesting that Duragesic has a lower potential for abuse compared  
15 to other opioid products.”

16 543. The September 2, 2004 letter warned Janssen regarding its claims  
17 that Duragesic had a low reported rate of mentions in the Drug Abuse Warning  
18 Network (“DAWN”) as compared to other opioids. The letter stated that the claim  
19 was false or misleading because the claim was not based on substantial data and  
20 because the lower rate of mentions was likely attributable to Duragesic’s lower  
21 frequency of use compared to other opioids listed in DAWN:

22 The file card presents the prominent claim, “Low reported rate  
23 of mentions in DAWN data,” along with Drug Abuse Warning  
24 Network (DAWN) data comparing the number of mentions for  
Fentanyl/combinations (710 mentions) to other listed opioid products,  
25 including Hydrocodone/combinations (21,567 mentions),  
Oxycodone/combinations (18,409 mentions), and Methadone (10,725  
26 mentions). The file card thus suggests that Duragesic is less abused  
than other opioid drugs.

27  
28 <sup>369</sup> *Id.* at 2-3.

<sup>370</sup> *Id.* at 3 (emphasis in original).

1 This is false or misleading for two reasons. First, we are not  
 2 aware of substantial evidence or substantial clinical experience to  
 3 support this comparative claim. The DAWN data cannot provide the  
 4 basis for a valid comparison among these products. As you know,  
 DAWN is not a clinical trial database. Instead, it is a national public  
 health surveillance system that monitors drug-related emergency  
 department visits and deaths. If you have other data demonstrating  
 that Duragesic is less abused, please submit them.

5 Second, Duragesic is not as widely prescribed as other opioid  
 6 products. As a result, the relatively lower number of mentions could  
 7 be attributed to the lower frequency of use, and not to a lower  
 incidence of abuse. The file card fails to disclose this information.<sup>371</sup>

8 544. The September 2, 2004 letter also detailed a series of unsubstantiated  
 9 false or misleading claims regarding Duragesic's effectiveness. The letter  
 10 concluded that various claims made by Janssen were insufficiently supported,  
 11 including:

- 12 • “Demonstrated effectiveness in chronic back pain with additional patient  
 13 benefits, . . . 86% of patients experienced overall benefit in a clinical study  
 14 based on: pain control, disability in ADLs, quality of sleep.”
- 15 • “All patients who experienced overall benefit from DURAGESIC would  
 16 recommend it to others with chronic low back pain.”
- 17 • “Significantly reduced nighttime awakenings.”
- 18 • “Significant improvement in disability scores as measured by the Oswestry  
 19 Disability Questionnaire and Pain Disability Index.”
- 20 • “Significant improvement in physical functioning summary score.”
- 21 • “Significant improvement in social functioning.”<sup>372</sup>

22 545. In addition, the September 2, 2004 letter identified “outcome claims  
 23 [that] are misleading because they imply that patients will experience improved  
 24 social or physical functioning or improved work productivity when using

26 <sup>371</sup> Warning Letter from Thomas W. Abrams, U.S. Department of Health and  
 27 Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc. (Sept. 2, 2004),  
 28 [https://www.pharmamedtechbi.com/~media/Images/Publications/Archive/The%20Pink%20Sheet/66/038/00660380018/040920\\_duragesic\\_letter.pdf](https://www.pharmamedtechbi.com/~media/Images/Publications/Archive/The%20Pink%20Sheet/66/038/00660380018/040920_duragesic_letter.pdf) at 2.

<sup>372</sup> *Id.* at 2-3.

1 Duragesic.” The claims include “‘1,360 loaves . . . and counting,’ ‘[w]ork,  
 2 uninterrupted,’ ‘[l]ife, uninterrupted,’ ‘[g]ame, uninterrupted,’ ‘[c]hronic pain  
 3 relief that supports functionality,’ ‘[h]elps patients think less about their pain,’ and  
 4 ‘[i]mprove[s] . . . physical and social functioning.’” The September 2, 2004 letter  
 5 stated: “Janssen has not provided references to support these outcome claims. We  
 6 are not aware of substantial evidence or substantial clinical experience to support  
 7 these claims.”<sup>373</sup>

8 546. On July 15, 2005, the FDA issued a public health advisory warning  
 9 doctors of deaths resulting from the use of Duragesic and its generic competitor,  
 10 manufactured by Mylan N.V. Plaintiffs are informed and believe that the advisory  
 11 noted that the FDA had been “‘examining the circumstances of product use to  
 12 determine if the reported adverse events may be related to inappropriate use of the  
 13 patch’” and noted the possibility “that patients and physicians might be unaware  
 14 of the risks” of using the fentanyl transdermal patch, which is a potent opioid  
 15 analgesic meant to treat chronic pain that does not respond to other painkillers.<sup>374</sup>

16 547. Finally, Cephalon has been the subject of investigations and  
 17 enforcement actions for its misrepresentations concerning Actiq. For example:

18 548. In October 2000, Cephalon acquired the worldwide product rights to  
 19 Actiq and began marketing and selling Actiq in the United States. The FDA  
 20 explicitly stated that Actiq “***must not*** be used in opioid non-tolerant patients,” was  
 21 contraindicated for the management of acute or postoperative pain, could be  
 22 deadly to children, and was “intended to be used only in the care of opioid-  
 23 tolerant cancer patients and only by oncologists and pain specialists who are  
 24 knowledgeable of and skilled in the use of Schedule II opioids to treat cancer  
 25

26  
 27 <sup>373</sup> *Id.* at 3.

28 <sup>374</sup> *New Fentanyl Warnings: More Needed to Protect Patients*, Institute for Safe  
 Medication Practices, August 11, 2005,  
<https://www.ismp.org/newsletters/acute care/articles/20050811.asp>

1 pain.”<sup>375</sup> The FDA also required that Actiq be provided only in compliance with a  
2 strict risk management program that explicitly limited the drug’s direct marketing  
3 to the approved target audiences, defined as oncologists, pain specialists, their  
4 nurses and office staff.<sup>376</sup>

5 549. Cephalon purchased the rights to Fentora, an even faster-acting tablet  
6 formulation of fentanyl, from Cima Labs, and submitted a new drug application to  
7 the FDA in August 2005. In September 2006, Cephalon received FDA approval to  
8 sell this faster-acting version of Actiq; but once again, concerned about the power  
9 and risks inherent to fentanyl, the FDA limited Fentora’s approval to the treatment  
10 of BTP in cancer patients who were already tolerant to around-the-clock opioid  
11 therapy for their underlying persistent cancer pain. Cephalon began marketing and  
12 selling Fentora in October 2006.

13 550. Due to the FDA’s restrictions, Actiq’s consumer base was limited, as  
14 was its potential for growing revenue. In order to increase its revenue and market  
15 share, Cephalon needed to find a broader audience and thus began marketing its  
16 lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer  
17 pain, targeting non-oncology practices, including, but not limited to, pain doctors,  
18 general practitioners, migraine clinics, anesthesiologists and sports clinics. It did  
19 so in violation of applicable regulations prohibiting the marketing of medications  
20 for off-label use and indirect contravention of the FDA’s strict instructions that  
21 Actiq be prescribed only to terminal cancer patients and by oncologists and pain  
22 management doctors experienced in treating cancer pain.

23 551. Beginning in or about 2003, former Cephalon employees filed four  
24 whistleblower lawsuits claiming the company had wrongfully marketed Actiq for  
25

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26 <sup>375</sup> *Id.*

27 <sup>376</sup> See John Carreyrou, *Narcotic “Lollipop” Becomes Big Seller Despite FDA*  
28 *Curbs*, Wall St. J. (Nov. 3, 2006), <https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fdacurbs/>.

1 unapproved off-label uses. On September 29, 2008, Cephalon finalized and  
 2 entered into a corporate integrity agreement with the Office of the Inspector  
 3 General of HHS and agreed to pay \$425 million in civil and criminal penalties for  
 4 its off-label marketing of Actiq and two other drugs (Gabitril and Provigil).

5 According to a DOJ press release, Cephalon trained sales representatives to  
 6 disregard restrictions of the FDA-approved label, employed sales representatives  
 7 and healthcare professionals to speak to physicians about off-label uses of the  
 8 three drugs and funded CME to promote off-label uses. Specifically, the DOJ  
 9 stated:

10 From 2001 through at least 2006, Cephalon was allegedly promoting  
 11 [Actiq] for non-cancer patients to use for such maladies as migraines,  
 12 sickle-cell pain crises, injuries, and in anticipation of changing wound  
 13 dressings or radiation therapy. Cephalon also promoted Actiq for use  
 in patients who were not yet opioid-tolerant, and for whom it could  
 have life-threatening results.<sup>377</sup>

14 552. Then-acting U.S. Attorney Laurie Magid commented on the dangers  
 15 of Cephalon's unlawful practices:

16 "This company subverted the very process put in place to protect the public  
 17 from harm, and put patients' health at risk for nothing more than boosting  
 18 its bottom line. People have an absolute right to their doctors' best medical  
 19 judgment. They need to know the recommendations a doctor makes are not  
 20 influenced by sales tactics designed to convince the doctor that the drug  
 21 being prescribed is safe for uses beyond what the FDA has approved."<sup>378</sup>

22 553. Upon information and belief, documents uncovered in the  
 23 government's investigations confirm that Cephalon directly targeted non-  
 24 oncology practices and pushed its sales representatives to market Actiq for off-  
 25 label use. For instance, the government's investigations confirmed:

26 \_\_\_\_\_  
 27 <sup>377</sup> Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon  
 To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008),  
 28 <https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

<sup>378</sup> *Id.*

- a. Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered “no,” a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- b. Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- c. Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a “high” and carries a low risk of diversion toward recreational use;
- d. Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;
- e. Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and
- f. Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.<sup>379</sup>

554. The FDA’s letters and safety alerts, the DOJ and state investigations, and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

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<sup>379</sup> John Carreyrou, Cephalon Used Improper Tactics to Sell Drug, Probe Finds, Wall St. J., Nov. 21, 2006, at B1 (hereinafter “Carreyrou, Cephalon Used Improper Tactics”).



1           555. On September 27, 2007, the FDA issued a public health advisory to  
2 address numerous reports that patients who did not have cancer or were not  
3 opioid-tolerant had been prescribed Fentora, and death or life-threatening side  
4 effects had resulted. The FDA warned: “Fentora should not be used to treat any  
5 type of short-term pain.”<sup>380</sup>

6           556. Nevertheless, in 2008, Cephalon pushed forward to expand the target  
7 base for Fentora and filed a supplemental drug application requesting FDA  
8 approval of Fentora for the treatment of non-cancer BTP. In the application and  
9 supporting presentations to the FDA, Cephalon admitted both that it knew the  
10 drug was heavily prescribed for off-label use and that the drug’s safety for such  
11 use had never been clinically evaluated.<sup>381</sup> An FDA advisory committee noted that  
12 Fentora’s existing risk management program was ineffective and stated that  
13 Cephalon would have to institute a risk evaluation and mitigation strategy for the  
14 drug before the FDA would consider broader label indications. In response,  
15 Cephalon revised Fentora’s label and medication guide to add strengthened  
16 warnings.

17           557. But in 2009, the FDA once again informed Cephalon that the risk  
18 management program was not sufficient to ensure the safe use of Fentora for  
19 already approved indications.

20           558. On March 26, 2009, the FDA warned Cephalon against its  
21 misleading advertising of Fentora (“Warning Letter”). The Warning Letter  
22

23 <sup>380</sup> Press Release, U.S. Food & Drug Administration, Public Health Advisory:  
24 Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept.  
25 26, 2007), <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

26 <sup>381</sup> FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life  
27 Support Drugs and  
28 Drug Safety and Risk Management Advisory Committee, U.S. Food & Drug  
Administration (May 6, 2008), <https://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-03-Cephalon.pdf>.

1 described a Fentora Internet advertisement as misleading because it purported to  
2 broaden “the indication for Fentora by implying that any patient with cancer who  
3 requires treatment for breakthrough pain is a candidate for Fentora . . . when this  
4 is not the case.”<sup>382</sup> Rather, Fentora was only indicated for those who were already  
5 opioid tolerant. It further criticized Cephalon’s other direct Fentora advertisements  
6 because they did not disclose the risks associated with the drug.

7 559. Flagrantly disregarding the FDA’s refusal to approve Fentora for  
8 non-cancer BTP and its warning against marketing the drug for the same,  
9 Cephalon continued to use the same sales tactics to push Fentora as it did with  
10 Actiq.

11 560. The misrepresentations disseminated by members of the Opioid  
12 Marketing Enterprise, and the RICO Marketing Defendants, caused The County  
13 and California consumers to pay for excessive opioid prescriptions, suffer injuries  
14 and losses, and to incur costs associated with the opioid epidemic caused by the  
15 Opioid Marketing Enterprise.

16 561. The RICO Marketing Defendants alone could not have accomplished  
17 the purpose of the Opioid Marketing Enterprise without the assistance of the Front  
18 Groups and KOLs, who were perceived as “neutral” and more “scientific” than  
19 the RICO Defendants themselves. Without these misrepresentations, the Opioid  
20 Marketing Enterprise could not have achieved its common purpose.

21 562. The impact of the Opioid Marketing Enterprise’s scheme is still in  
22 place – i.e., the opioids continue to be prescribed and used for chronic pain  
23 throughout the State of California, and the epidemic continues to injure The  
24 County, and consume the resources of The County’s and California’s health care  
25 and law enforcement systems.

26  
27  
28 <sup>382</sup> Letter from Michael Sauers, Regulatory Review Officer, Division of Drug  
Marketing, Advertising and Communications, to Carole S. Marchione, Senior  
Director and Group Leader, Regulatory Affairs (March 26, 2009)

1           563. The foregoing evidences that the RICO Marketing Defendants, the  
2 Front Groups, and the KOLs were each willing participants in the Opioid  
3 Marketing Enterprise, had a common purpose and interest in the object of the  
4 scheme, and functioned within a structure designed to effectuate the Enterprise's  
5 purpose.

6           **B. CONDUCT OF THE OPIOID MARKETING ENTERPRISE.**

7           564. During time period described in this Complaint, from approximately  
8 the late 1990s to the present, the RICO Marketing Defendants exerted control over  
9 the Opioid Marketing Enterprise and participated in the operation or management  
10 of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the  
11 following ways:

- 12           a. Creating a body of deceptive, misleading and unsupported medical and  
13 popular literature about opioids that (a) understated the risks and  
14 overstated the benefits of long-term use; (b) appeared to be the result of  
15 independent, objective research; and (c) was thus more likely to be  
16 relied upon by physicians, patients, and payors;
- 17           b. Creating a body of deceptive, misleading and unsupported electronic and  
18 print advertisements about opioids that (a) understated the risks and  
19 overstated the benefits of long-term use; (b) appeared to be the result of  
20 independent, objective research; and (c) was thus more likely to be  
21 relied upon by physicians, patients, and payors;
- 22           c. Creating a body of deceptive, misleading and unsupported sales and  
23 promotional training materials about opioids that (a) understated the  
24 risks and overstated the benefits of long-term use; (b) appeared to be the  
25 result of independent, objective research; and (c) was thus more likely to  
26 be relied upon by physicians, patients, and payors;
- 27           d. Creating a body of deceptive, misleading and unsupported CMEs and  
28 speaker presentations about opioids that (a) understated the risks and

- 1           overstated the benefits of long-term use; (b) appeared to be the result of  
2           independent, objective research; and (c) was thus more likely to be  
3           relied upon by physicians, patients, and payors;
- 4           e. Selecting, cultivating, promoting and paying KOLs based solely on their  
5           willingness to communicate and distribute the RICO Defendants'  
6           messages about the use of opioids for chronic pain;
- 7           f. Providing substantial opportunities for KOLs to participate in research  
8           studies on topics the RICO Defendants suggested or chose, with the  
9           predictable effect of ensuring that many favorable studies appeared in  
10          the academic literature;
- 11          g. Paying KOLs to serve as consultants or on the RICO Defendants'  
12          advisory boards, on the advisory boards and in leadership positions on  
13          Front Groups, and to give talks or present CMEs, typically over meals or  
14          at conferences;
- 15          h. Selecting, cultivating, promoting, creating and paying Front Groups  
16          based solely on their willingness to communicate and distribute the  
17          RICO Defendants' messages about the use of opioids for chronic pain;
- 18          i. Providing substantial opportunities for Front Groups to participate in  
19          and/or publish research studies on topics the RICO Defendants  
20          suggested or chose (and paid for), with the predictable effect of  
21          ensuring that many favorable studies appeared in the academic  
22          literature;
- 23          j. Paying significant amounts of money to the leaders and individuals  
24          associated with Front Groups;
- 25          k. Donating to Front Groups to support talks or CMEs, that were typically  
26          presented over meals or at conferences;
- 27  
28

- 1 l. Disseminating many of their false, misleading, imbalanced, and
- 2 unsupported statements through unbranded materials that appeared to
- 3 be independent publications from Front Groups;
- 4 m. Sponsoring CME programs put on by Front Groups that focused
- 5 exclusively on the use of opioids for chronic pain;
- 6 n. Developing and disseminating pro-opioid treatment guidelines with the
- 7 help of the KOLs as authors and promoters, and the help of the Front
- 8 Groups as publishers, and supporters;
- 9 o. Encouraging Front Groups to disseminate their pro-opioid messages to
- 10 groups targeted by the RICO Defendants, such as veterans and the
- 11 elderly, and then funded that distribution;
- 12 p. Concealing their relationship to and control of Front Groups and KOLs
- 13 from the The County and the public at large; and
- 14 q. Intending that Front Groups and KOLs would distribute through the
- 15 U.S. mail and interstate wire facilities, promotional and other materials
- 16 that claimed opioids could be safely used for chronic pain.

17 565. The Front Groups also participated in the conduct of the Opioid  
18 Marketing Enterprise, directly or indirectly, in the following ways:

- 19 a. The Front Groups promised to, and did, make representations regarding
- 20 opioids and the RICO Marketing Defendants' drugs that were consistent
- 21 with the RICO Marketing Defendants' messages;
- 22 b. The Front Groups distributed, through the U.S. Mail and interstate wire
- 23 facilities, promotional and other materials which claimed that opioids
- 24 could be safely used for chronic pain without addiction, and
- 25 misrepresented the benefits of using opioids for chronic pain outweighed
- 26 the risks;
- 27
- 28

- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

566. The RICO Marketing Defendants’ Front Groups, “with their large numbers and credibility with policymakers and the public—have ‘extensive influence in specific disease areas.’” The RICO Marketing Defendants’ larger Front Groups “likely have a substantial effect on policies relevant to their industry sponsors.”<sup>383</sup> “By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic.”<sup>384</sup>

567. The KOLs also participated, on information and belief, in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants’ drugs that were consistent with the RICO Marketing Defendants’ messages themselves;

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<sup>383</sup> *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, February 12, 2018 <https://www.hsd.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at 1.

<sup>384</sup> *Id.* 2.



- b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The KOLs concealed their connections to the Front Groups and the RICO Defendants, and their sponsorship by the RICO Marketing Defendants.

568. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

### **C. PATTERN OF RACKETEERING ACTIVITY**

569. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

1           570. The RICO Marketing Defendants committed, conspired to commit,  
2 and/or aided and abetted in the commission of at least two predicate acts of  
3 racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the  
4 past ten years. The multiple acts of racketeering activity that the RICO Marketing  
5 Defendants committed, or aided and abetted in the commission of, were related to  
6 each other, posed a threat of continued racketeering activity, and therefore  
7 constitute a “pattern of racketeering activity.” The racketeering activity was made  
8 possible by the RICO Marketing Defendants’ regular use of the facilities, services,  
9 distribution channels, and employees of the Opioid Marketing Enterprise, the U.S.  
10 Mail and interstate wire facilities. The RICO Marketing Defendants participated  
11 in the scheme to defraud by using mail, telephones and the Internet to transmit  
12 mailings and wires in interstate or foreign commerce.

13           571. The pattern of racketeering activity described herein used by the  
14 RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved  
15 thousands of separate instances of the use of the U.S. Mail or interstate wire  
16 facilities in furtherance of the unlawful Opioid Marketing Enterprise, including  
17 virtually uniform misrepresentations, concealments and material omissions  
18 regarding the beneficial uses and non-addictive qualities for the long-term  
19 treatment of chronic, non-acute and non-cancer pain, with the goal of profiting  
20 from increased sales of the RICO Marketing Defendants’ drugs induced by  
21 consumers, prescribers, regulators and the County’s reliance on the RICO  
22 Marketing Defendants’ misrepresentations.

23           572. Each of these fraudulent mailings and interstate wire transmissions  
24 constitutes racketeering activity and collectively, these violations constitute a  
25 pattern of racketeering activity, through which Defendants, the Front Groups and  
26 the KOLs defrauded and intended to defraud California consumers, the State, and  
27 other intended victims.  
28

1           573. In devising and executing the illegal scheme, the RICO Marketing  
2 Defendants devised and knowingly carried out a material scheme and/or artifice to  
3 defraud by means of materially false or fraudulent pretenses, representations,  
4 promises, or omissions of material facts regarding the safe, non-addictive and  
5 effective use of opioids for long-term chronic, non-acute and non-cancer pain.  
6 The RICO Marketing Defendants and members of the Opioid Marketing  
7 Enterprise knew that these representations violated the FDA approved use these  
8 drugs, and were not supported by actual evidence. For the purpose of executing  
9 the illegal scheme, the RICO Marketing Defendants intended that that their  
10 common purpose and scheme to defraud would, and did, use the U.S. Mail and  
11 interstate wire facilities, intentionally and knowingly with the specific intent to  
12 advance their illegal scheme.

13           574. The RICO Marketing Defendants' predicate acts of racketeering (18  
14 U.S.C. § 1961(1)) include, but are not limited to:

15           a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341  
16 by sending or receiving, or by causing to be sent and/or received,  
17 materials via U.S. mail or commercial interstate carriers for the purpose  
18 of executing the unlawful scheme to design, manufacture, market, and  
19 sell the prescription opioids by means of false pretenses,  
20 misrepresentations, promises, and omissions.

21           b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343  
22 by transmitting and/or receiving, or by causing to be transmitted and/or  
23 received, materials by wire for the purpose of executing the unlawful  
24 scheme to design, manufacture, market, and sell the prescription opioids  
25 by means of false pretenses, misrepresentations, promises, and  
26 omissions.

27           575. Each instance of racketeering activity alleged herein was related, had  
28 similar purposes, involved the same or similar participants and methods of

1 commission, and had similar results affecting similar victims, including California  
2 consumers, prescribers, regulators and The County. The RICO Marketing  
3 Defendants, Front Groups and KOLs calculated and intentionally crafted the  
4 scheme and common purpose of the Opioid Marketing Enterprise to ensure their  
5 own profits remained high. In designing and implementing the scheme, the RICO  
6 Marketing Defendants understood and intended that those in the distribution chain  
7 rely on the integrity of the pharmaceutical companies and ostensibly neutral third  
8 parties to provide objective and scientific evidence regarding the RICO Marketing  
9 Defendants' products.

10 576. By intentionally misrepresenting the risks and benefits of using  
11 opioids for chronic pain, and then subsequently failing to disclose such practices  
12 to California consumers, prescribers, regulators and The County. Defendants, the  
13 Front Groups and the KOLs engaged in a fraudulent and unlawful course of  
14 conduct constituting a pattern of racketeering activity.

15 577. The racketeering activities conducted by the RICO Marketing  
16 Defendants, Front Groups and KOLs amounted to a common course of conduct,  
17 with a similar pattern and purpose, intended to deceive California consumers,  
18 prescribers, regulators and The County. Each separate use of the U.S. Mail and/or  
19 interstate wire facilities employed by Defendants was related, had similar intended  
20 purposes, involved similar participants and methods of execution, and had the  
21 same results affecting the same victims, including California consumers,  
22 prescribers, regulators and The County. The RICO Marketing Defendants have  
23 engaged in the pattern of racketeering activity for the purpose of conducting the  
24 ongoing business affairs of the Opioid Marketing Enterprise.

25 578. The RICO Marketing Defendants' pattern of racketeering activity  
26 alleged herein and the Opioid Marketing Enterprise are separate and distinct from  
27 each other. Likewise, the RICO Marketing Defendants are distinct from the  
28 Opioid Marketing Enterprise.

1           579. The pattern of racketeering activity alleged herein is continuing as of  
2 the date of this complaint, and, upon information and belief, will continue into the  
3 future unless enjoined by this Court.

4           580. Many of the precise dates of the Opioid Marketing Enterprise's uses  
5 of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of  
6 mail and wire fraud) have been hidden and cannot be alleged without access to the  
7 books and records maintained by the RICO Marketing Defendants, Front Groups,  
8 and KOLs. Indeed, an essential part of the successful operation of the Opioid  
9 Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiffs  
10 have described the occasions on which the RICO Marketing Defendants, Front  
11 Groups, and KOLs disseminated misrepresentations and false statements to  
12 California consumers, prescribers, regulators and The County, and how those acts  
13 were in furtherance of the scheme, and do so further below.

14           581. The RICO Marketing Defendants' use of the U.S. Mail and interstate  
15 wire facilities to perpetrate the opioids marketing scheme involved thousands of  
16 communications, publications, representations, statements, electronic  
17 transmissions, payments, including, *inter alia*:

18           a. Marketing materials about opioids, and their risks and benefits, which  
19 the RICO Marketing Defendants sent to health care providers,  
20 transmitted through the internet and television, published, and  
21 transmitted to Front Groups and KOLs located across the country and  
22 the State;

23           b. Written representations and telephone calls between the RICO  
24 Marketing Defendants and Front Groups regarding the  
25 misrepresentations, marketing statements and claims about opioids,  
26 including the non-addictive, safe use of chronic long-term pain  
27 generally;  
28

- c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;
- f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities – the wrongful proceeds of the scheme.

582. In addition to the above-referenced predicate acts, it was foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and,



1 in those publications, claim that the benefits of using opioids for chronic pain  
2 outweighed the risks of doing so.

3 583. The RICO Marketing Defendants aided and abetted others in the  
4 violations of the above laws, thereby rendering them indictable as principals in the  
5 18 U.S.C. §§ 1341 and 1343 offenses.

6 584. To achieve the common goal and purpose of the Opioid Marketing  
7 Enterprise, the RICO Marketing Defendants and members of the Opioid  
8 Marketing Enterprise hid from the consumers, prescribers, regulators and The  
9 County: (1) the fraudulent nature of the RICO Marketing Defendants' marketing  
10 scheme; (2) the fraudulent nature of statements made by the RICO Marketing  
11 Defendants and by their KOLs, Front Groups and other third parties regarding the  
12 safety and efficacy of prescription opioids; and (3) the true nature of the  
13 relationship between the members of the Opioid Marketing Enterprise.

14 585. The RICO Marketing Defendants, and each member of the Opioid  
15 Marketing Enterprise agreed, with knowledge and intent, to the overall objective  
16 of the RICO Marketing Defendants' fraudulent scheme and participated in the  
17 common course of conduct to commit acts of fraud and indecency in marketing  
18 prescription opioids.

19 586. Indeed, for the RICO Marketing Defendants' fraudulent scheme to  
20 work, each of the RICO Marketing Defendants had to agree to implement similar  
21 tactics regarding fraudulent marketing of prescription opioids. This conclusion is  
22 supported by the fact that the RICO Marketing Defendants each financed,  
23 supported, and worked through the same KOLs and Front Groups, and often  
24 collaborated on and mutually supported the same publications, CMEs,  
25 presentations, and prescription guidelines.

26 587. As described herein, the RICO Marketing Defendants engaged in a  
27 pattern of related and continuous predicate acts for years. The predicate acts  
28 constituted a variety of unlawful activities, each conducted with the common

1 purpose of obtaining significant money and revenue from the marketing and sale  
2 of their highly addictive and dangerous drugs. The predicate acts also had the  
3 same or similar results, participants, victims, and methods of commission. The  
4 predicate acts were related and not isolated events.

5 588. The RICO Marketing Defendants predicate acts all had the purpose  
6 of creating the opioid epidemic that substantially injured The County's business  
7 and property, while simultaneously generating billion-dollar revenue and profits  
8 for the RICO Marketing Defendants. The predicate acts were committed or caused  
9 to be committed by the RICO Marketing Defendants through their participation in  
10 the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

11 589. The RICO Marketing Defendants' predicate acts and pattern of  
12 racketeering activity were a substantial and foreseeable cause of The County's  
13 injury and the relationship between the RICO Marketing Defendants' conduct and  
14 The County's injury is logical and not speculative. It was foreseeable to the RICO  
15 Marketing Defendants that when they fraudulently marketed highly-addictive and  
16 dangerous drugs, that were approved for very limited and specific uses by the  
17 FDA, as non-addictive and safe for off-label uses such as moderate pain, non-  
18 cancer pain, and long-term chronic pain, that the RICO Marketing Defendants  
19 would create an opioid-addiction epidemic that logically, substantially and  
20 foreseeably harmed The County.

21 590. The pattern of racketeering activity alleged herein is continuing as of  
22 the date of this Complaint and, upon information and belief, will continue into the  
23 future unless enjoined by this Court. The last racketeering incident occurred  
24 within five years of the commission of a prior incident of racketeering.

## 25 **D. DAMAGES.**

### 26 **1. Impact of the Opioid Marketing Enterprise.**

27 591. California has been especially ravaged by the national opioid crisis.  
28

592. More people die each year from drug overdoses in California than in any other state.<sup>385</sup> The State's death rate has continued to climb, increasing by 30 percent from 1999 to 2015, according to the Center for Disease Control (CDC).<sup>386</sup>

593. In 2016, 1,925 Californians died due to prescription opioids.<sup>387</sup> This number is on par with other recent years: in 2015, 1,966 deaths in California were due just to prescription opioids (not including heroin); in 2014 that number was even higher at 2,024 prescription opioid deaths; and in 2013, 1,934 Californians died from a prescription opioid overdose.<sup>388</sup>

594. Of the 1,925 opioid-related deaths in California in 2016, fentanyl was a factor in at least 234 of them.<sup>389</sup> This is an increase of 47 percent for 2016.<sup>390</sup> Heroin-related deaths have risen by 67 percent in California since 2006.<sup>391</sup>

595. The high number of deaths is due in part to the extraordinary number of opioids prescribed in the State. Over 23.6 million prescriptions for opioids were written in California in just 2016.<sup>392</sup>

596. The California Department of Public Health tracks the number of reported hospitalizations and emergency department visits due to prescription opioids.<sup>393</sup> In 2015, the last year for which information is currently available,

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<sup>385</sup> Davis, *supra*.

<sup>386</sup> Karlamangla, *supra*.

<sup>387</sup> Davis, *supra*.

<sup>388</sup> California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, *supra*.

<sup>389</sup> Davis, *supra*.

<sup>390</sup> Karlamangla, *supra*.

<sup>391</sup> California Department of Public Health, *State of California Strategies to Address Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in California* at 3 (June 2016), available at <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Documents/Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited March 2, 2018).

<sup>392</sup> California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, *supra*.

<sup>393</sup> *Id.*

1 California had 3,935 emergency department visits and 4,095 hospitalizations  
 2 related to prescription opioid overdoses (excluding heroin).<sup>394</sup> The numbers were  
 3 even higher in 2014, when 4,106 people visited the emergency department and  
 4 4,482 people were hospitalized due to prescription opioid abuse.<sup>395</sup> In 2013, there  
 5 were 3,964 emergency department visits and 4,344 hospitalizations for  
 6 prescription opioid overdoses.<sup>396</sup> When emergency visits and hospitalizations  
 7 include heroin, the numbers are even higher.<sup>397</sup>

8 597. Neonatal Abstinence Syndrome (NAS) has increased dramatically in  
 9 California, with the rate of infants born with NAS more than tripling from 2008 to  
 10 2013.<sup>398</sup> While the number of affected newborns rose from 1,862 in 2008 to 3,007  
 11 in 2014, that number jumped by another 21 percent in 2015.<sup>399</sup> This is despite a  
 12 steady decline in the overall number of births in California during that same  
 13 time.<sup>400</sup>

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24 <sup>394</sup> *Id.*

25 <sup>395</sup> *Id.*

26 <sup>396</sup> *Id.*

27 <sup>397</sup> *Id.*

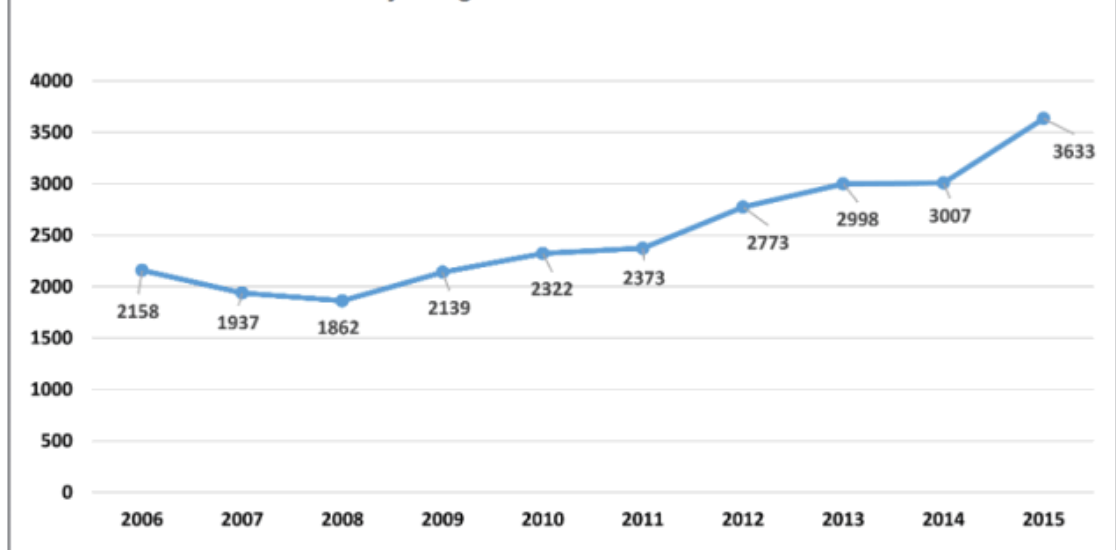
28 <sup>398</sup> California Child Welfare Co-Investment Partnership, *supra* at 5.

<sup>399</sup> Clark, *supra*.

<sup>400</sup> *Id.*



Newborns Affected by Drugs\* Transmitted Via Placenta or Breast Milk



\*Includes cocaine, hallucinogenic agents, other narcotics, other drugs of addiction, or noxious substances, or those that displayed withdrawal symptoms of the same.  
Source: Inpatient Discharge Data, 2006 – 2015; Office of Statewide Health Planning and Development

598. Reports from California's Office of Statewide Health Planning, which collects data from licensed health care facilities, have shown a 95 percent increase between 2008 and 2015 of newborns affected by drugs transmitted via placenta or breast milk.<sup>401</sup>

599. The opioid epidemic has also had an impact on crime in California. Pharmacy robberies have gone up by 163 percent in California over the last two years, according to the DEA. The DEA recorded 90 incidents in 2015, 154 in 2016 and, through mid-November of 2017, that number had climbed to 237.<sup>402</sup>

<sup>401</sup> California Child Welfare Co-Investment Partnership, *supra*.

<sup>402</sup> Ed Fletcher, "What's behind the spike in drug store robberies?" *The Sacramento Bee*, Dec. 8, 2017 (available at <http://www.sacbee.com/news/local/crime/article188636384.html> (last visited March 2, 2018)).

1 Most perpetrators were after prescription opioids.<sup>403</sup> In addition, fentanyl seizures  
 2 at California ports increased 266 percent in fiscal year 2017.<sup>404</sup>

3 600. The opioid epidemic is particularly devastating in Plaintiffs'  
 4 Community.

5 601. In 2016, the County endured 17 deaths due to opioid overdoses, for a  
 6 death rate of 17.3 per 100,000 people, the fifth highest in the State.<sup>405</sup> In 2015, the  
 7 County's opioid overdose death rate was in the highest quartile in the State with a  
 8 rate of 15 deaths per 100,000 residents.<sup>406</sup> In 2014 the death rate was 16.96.<sup>407</sup>

9 602. This is part of a long-standing trend. From 2009 to 2013, the County  
 10 had 38 deaths due to opioid pharmaceuticals, for the ninth highest death rate in the  
 11 State.<sup>408</sup>

12 603. From 2012 to 2014, the County suffered 52 deaths due to drug  
 13 overdoses for a drug overdose mortality rate of 20 deaths per 100,000 residents.<sup>409</sup>

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 15 <sup>403</sup> *Id.*

16 <sup>404</sup> United State Department of Justice, The United States Attorney's Office,  
 17 Southern District of California, *U.S. Attorney Appoints Opioid Coordinators* (Feb.  
 18 8, 2018) available at [https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-](https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators)  
 19 [opioid-coordinators](https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators) (last visited March 2, 2018).

20 <sup>405</sup> California Department of Public Health, *California Opioid Overdose*  
 21 *Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last  
 22 visited April 20, 2018) (Mendocino County specific page).

23 <sup>406</sup> Public Health Institute, Tackling An Epidemic: An Assessment of the California  
 24 Opioid Safety Coalitions Network, at p. 11, available at  
 25 <https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27ttdpzxmbclj7cxq99alz.pdf> (last visited April 20, 2018); *see also* Safe Rx  
 26 Mendocino, Opioid Safety Coalition, available at  
 27 <https://www.saferxmendocino.com/> (last visited April 21, 2018).

28 <sup>407</sup> Safe Rx Mendocino, Opioid Safety Coalition, available at  
<https://www.saferxmendocino.com/> (last visited April 21, 2018).

<sup>408</sup> California Department of Public Health, *State of California Strategies to*  
*Address Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in*  
*California* at 4 (June 2016), available at  
[https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Documen](https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Documents/Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf)  
[t%20Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventio](https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Documents/Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf)  
[nStrategies4.17.pdf](https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Documents/Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf) (last visited April 20, 2018).

<sup>409</sup> County Health Rankings & Roadmaps, Drug overdose deaths, available at  
[http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/dat](http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/data)  
[a](http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/data) (last visited April 20, 2018).



1           604. Prescription opioids have also been responsible for a high rate of  
2 emergency department visits in the County. In 2016, Mendocino County had a  
3 rate of 30.6 emergency department visits per 100,000 residents due to opioid  
4 overdoses (excluding heroin).<sup>410</sup>

5           605. The CDC has tracked prescription rates per county in the United  
6 States, identifying the geographic “hotspots” for rates of opioid prescriptions.<sup>411</sup>  
7 The CDC has calculated the geographic distribution at county levels of opioid  
8 prescriptions dispensed per 100 persons,<sup>412</sup> revealing that Mendocino County has  
9 been a consistent hotspot over at least the past decade.

10           606. The CDC’s statistics prove that the opioid prescription rates in  
11 Mendocino County have exceeded any legitimate medical, scientific, or industrial  
12 purpose. The overall opioid prescribing rate in 2016 was 66.5 prescriptions per  
13 100 people and 44.8 in California.<sup>413</sup> However, in Mendocino County, California,  
14 the 2016 prescription rate was 105.1 per 100 people – more than one prescription  
15 for every man, woman and child in Mendocino County and one of the highest  
16 prescribing rates in the State.<sup>414</sup> This is down from the 2015 prescribing rate for  
17 Mendocino County which was 118.2 per 100 people.<sup>415</sup>

18  
19 <sup>410</sup> California Department of Public Health, *California Opioid Overdose*  
20 *Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last  
visited April 20, 2018) (Mendocino County specific page).

21 <sup>411</sup> U.S. Prescribing Rate Maps, CDC, available at  
22 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
2017).

23 <sup>412</sup> *Id.*

24 <sup>413</sup> *Id.* See also U.S. State Prescribing Rates, 2016, available at  
<https://www.cdc.gov/drugoverdose/maps/rxstate2016.html> (last visited April 18,  
2018).

25 <sup>414</sup> U.S. County Prescribing Rates, 2016, (reporting for “Mendocino, CA” here and  
26 below) CDC available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited April 18,  
2018).

27 <sup>415</sup> U.S. County Prescribing Rates, 2015, CDC, available at  
28 <https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html> (last visited April 18,  
2018).

607. Unfortunately, the 2015 and 2016 high rates of opioid prescriptions were not an aberration for Mendocino County. Consistently, the opioid prescribing rates in Mendocino County have been among the highest in the state, significantly greater than the national and state averages, and well more than one prescription per person living in the County. Compared to a national average of 75.6 opioid prescriptions per 100 people in 2014<sup>416</sup> and 52.7 in California,<sup>417</sup> the Mendocino County opioid prescription rate was 127.2 per 100 people.<sup>418</sup> In 2013, the national average was 78.1 opioid prescriptions per 100 people,<sup>419</sup> but the opioid prescription rate in Mendocino County was 129.4 per 100 people.<sup>420</sup> Compared to a national average of 81.3 opioid prescriptions per 100 people in 2012,<sup>421</sup> the opioid prescription rate in Mendocino County was 137.2 per 100 people that year – an all-time high for Mendocino County.<sup>422</sup> In 2011, the national average was 80.9 opioid prescriptions per 100 people,<sup>423</sup> but the opioid

<sup>416</sup> U.S. Prescribing Rate Maps, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30, 2017).

<sup>417</sup> U.S. State Prescribing Rates, 2014, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2014.html> (last visited Dec. 11, 2017).

<sup>418</sup> U.S. County Prescribing Rates, 2014, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html> (last visited April 18, 2018).

<sup>419</sup> U.S. Prescribing Rate Maps, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30, 2017).

<sup>420</sup> U.S. County Prescribing Rates, 2013, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2013.html> (last visited April 18, 2018).

<sup>421</sup> U.S. Prescribing Rate Maps, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30, 2017).

<sup>422</sup> U.S. County Prescribing Rates, 2012, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html> (last visited April 18, 2018).

<sup>423</sup> U.S. Prescribing Rate Maps, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30, 2017).

1 prescription rate in Mendocino County was 137 per 100 people.<sup>424</sup> Compared to a  
 2 national average of 81.2 opioid prescriptions per 100 people in 2010,<sup>425</sup> the  
 3 Mendocino County opioid prescription rate was 135.1 per 100 people.<sup>426</sup> In 2009,  
 4 the national average was 79.5 opioid prescriptions per 100 people,<sup>427</sup> but the rate  
 5 in Mendocino County was 129.4.5 per 100.<sup>428</sup> Compared to a national average of  
 6 78.2 opioid prescriptions per 100 people in 2008<sup>429</sup> and 55.1 in California,<sup>430</sup> the  
 7 Mendocino County rate was 128.6 per 100 people.<sup>431</sup> In 2007, the national  
 8 average was 75.9 opioid prescriptions per 100 people,<sup>432</sup> but the Mendocino  
 9 County rate was 121.6 per 100 people.<sup>433</sup> Compared to a national average of 72.4

11  
 12 <sup>424</sup> U.S. County Prescribing Rates, 2011, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html> (last visited April 18,  
 13 2018).

14 <sup>425</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 15 2017).

16 <sup>426</sup> U.S. County Prescribing Rates, 2010, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html> (last visited April 18,  
 17 2018).

18 <sup>427</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 19 2017).

20 <sup>428</sup> U.S. County Prescribing Rates, 2009, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2009.html> (last visited April 18,  
 21 2018).

22 <sup>429</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 23 2017).

24 <sup>430</sup> U.S. State Prescribing Rates, 2008, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxstate2008.html> (last visited Dec. 11,  
 25 2017).

26 <sup>431</sup> U.S. County Prescribing Rates, 2008, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2008.html> (last visited April 18,  
 27 2018).

28 <sup>432</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,,  
 2017).

<sup>433</sup> U.S. County Prescribing Rates, 2007, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2007.html> (last visited April 18,  
 2018).

1 opioid prescriptions per 100 people prescribed opioids in 2006,<sup>434</sup> the Mendocino  
 2 County rate was 114.1 per 100 people.<sup>435</sup>

## 3 **2. Relief Sought.**

4 608. The RICO Marketing Defendants' violations of law and their pattern  
 5 of racketeering activity directly and proximately caused The County injury in its  
 6 business and property. The RICO Marketing Defendants' pattern of racketeering  
 7 activity logically, substantially and foreseeably caused an opioid epidemic. The  
 8 County's injuries, as described below, were not unexpected, unforeseen or  
 9 independent.<sup>436</sup> Rather, as Plaintiffs allege, the RICO Marketing Defendants  
 10 knew that the opioids were unsuited to treatment of long-term chronic, non-acute,  
 11 and non-cancer pain, or for any other use not approved by the FDA, and knew that  
 12 opioids were highly addictive and subject to abuse.<sup>437</sup> Nevertheless, the RICO  
 13 Marketing Defendants engaged in a scheme of deception, that utilized the mail  
 14 and wires as part of their fraud, in order to increase sales of their opioid products.

15 609. It was foreseeable and expected that a massive marketing campaign  
 16 utilized by the RICO Marketing Defendants that misrepresented the non-addictive  
 17 and effective use of prescription opioids for purposes for which they are not suited  
 18 and not approved by the FDA would lead to a nationwide opioid epidemic.<sup>438</sup> It  
 19 was also foreseeable and expected that the RICO Marketing Defendants'  
 20 marketing campaign would lead to increased opioid addiction and overdose.<sup>439</sup>

21  
 22 <sup>434</sup> U.S. Prescribing Rate Maps, CDC, available at  
 23 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 2017).

24 <sup>435</sup> U.S. County Prescribing Rates, 2006, CDC, available at  
 25 <https://www.cdc.gov/drugoverdose/maps/rxcounty2006.html> (last visited April 18,  
 2018).

26 <sup>436</sup> Traveler's Property Casualty Company of America v. Actavis, Inc., 22 Cal.  
 Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

27 <sup>437</sup> *Id.*

28 <sup>438</sup> *Id.*

<sup>439</sup> *Id.*

1 The County's injuries were logically, foreseeable, and substantially caused by the  
2 opioid epidemic that the RICO Marketing Defendants created.

3 610. Specifically, the RICO Marketing Defendants' predicate acts and  
4 pattern of racketeering activity caused the opioid epidemic which has injured The  
5 County in the form of substantial losses of money and property that logically,  
6 directly and foreseeably arise from the opioid-addiction epidemic. The County's  
7 injuries, as alleged throughout this complaint, and expressly incorporated herein  
8 by reference, include:

- 9 a. Losses caused by purchasing and/or paying reimbursements for the  
10 RICO Marketing Defendants' prescription opioids, that The County  
11 would not have paid for or purchased but for the RICO Marketing  
12 Defendants' conduct;
- 13 b. Losses caused by the decrease in funding available for The County's  
14 public services for which funding was lost because it was diverted to  
15 other public services designed to address the opioid epidemic;
- 16 c. Costs for providing healthcare and medical care, additional therapeutic,  
17 and prescription drug purchases, and other treatments for patients  
18 suffering from opioid-related addiction or disease, including overdoses  
19 and deaths;
- 20 d. Costs of training emergency and/or first responders in the proper  
21 treatment of drug overdoses;
- 22 e. Costs associated with providing police officers, firefighters, and  
23 emergency and/or first responders with Naloxone – an opioid antagonist  
24 used to block the deadly effects of opioids in the context of overdose;
- 25 f. Costs associated with emergency responses by police officers,  
26 firefighters, and emergency and/or first responders to opioid overdoses;

- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- i. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- j. Costs associated with increased burden on the County's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- k. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- l. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' Community;
- m. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- n. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

611. The County's injuries were proximately caused by the RICO Marketing Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of The County's injuries. But for the opioid-



1 addiction epidemic created by the RICO Marketing Defendants' conduct, The  
2 County would not have lost money or property.

3 612. The County's injuries were directly caused by the RICO Marketing  
4 Defendants' pattern of racketeering activities.

5 613. The County is the most directly harmed entity and there is no other  
6 Plaintiff better suited to seek a remedy for the economic harms at issue here.

7 614. Plaintiff seeks all legal and equitable relief as allowed by law,  
8 including *inter alia* actual damages, treble damages, equitable relief, forfeiture as  
9 deemed proper by the Court, attorney's fees and all costs and expenses of suit and  
10 pre- and post-judgment interest.

11 **COUNT IV**

12 **RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT**

13 **18 U.S.C. 1961, et seq.**

14 **(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis,**

15 **McKesson, Cardinal, and AmerisourceBergen)**

16 **(The "Opioid Diversion Enterprise")**

17 615. Plaintiff, The County, hereby incorporates by reference all other  
18 paragraphs of this Complaint as if fully set forth herein, and further alleges as  
19 follows.

20 616. The County brings this Claim against the following Defendants, as  
21 defined above: Purdue, Cephalon, Endo, Mallinckrodt, Actavis (the  
22 "Manufacturer Defendants"), McKesson, Cardinal, and AmerisourceBergen (the  
23 "Distributor Defendants") (collectively, for purposes of this Claim, the "RICO  
24 Diversion Defendants").

25 617. The RICO Diversion Defendants conducted and continue to conduct  
26 their business through legitimate and illegitimate means in the form of an  
27 association-in-fact enterprise and/or a legal entity enterprise as defined in 18  
28 U.S.C. § 1961(4). Alternatively, the RICO Diversion Defendants were members

1 of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4).  
 2 Specifically, each of the RICO Diversion Defendants was a member of the  
 3 Healthcare Distribution Alliance (the “HDA”)<sup>440</sup> which is a distinct legal entity  
 4 that satisfies the definition of a RICO enterprise because it is a non-profit  
 5 corporation and, therefore, and “enterprise” within the definition set out in 18  
 6 U.S.C. § 1961(4). On information and belief, each of the RICO Diversion  
 7 Defendants is a member, participant, and/or sponsor of the HDA and utilized the  
 8 HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of  
 9 racketeering activity that gives rise to this cause of action. The legal and  
 10 association-in-fact enterprises alleged in the previous and subsequent paragraphs  
 11 are pleaded in the alternative and are collectively referred to as the “Opioid  
 12 Diversion Enterprise.”

13 618. For over a decade, the RICO Diversion Defendants aggressively  
 14 sought to bolster their revenue, increase profit, and grow their share of the  
 15 prescription painkiller market by unlawfully and surreptitiously increasing the  
 16 volume of opioids they sold. However, the RICO Diversion Defendants are not  
 17 permitted to engage in a limitless expansion of their sales through the unlawful  
 18 sales of regulated painkillers. As “registrants” under the Controlled Substances  
 19 Act, 21 U.S.C. § 821, *et seq.* (the “CSA”), the RICO Diversion Defendants  
 20 operated and continue to operate within a “closed-system.” The CSA restricts the  
 21 RICO Diversion Defendants’ ability to manufacture or distribute Schedule II  
 22 substances like opioids by: (1) requiring them to make sales within a limited quota  
 23 set by the DEA for the overall production of Schedule II substances like opioids;  
 24 (2) register to manufacture or distribute opioids; (3) maintain effective controls  
 25 against diversion of the controlled substances that they manufacturer or distribute;  
 26

27 <sup>440</sup> Health Distribution Alliance, History, Health Distribution Alliance, (last  
 28 accessed on September 15, 2017),  
<https://www.healthcaredistribution.org/about/hda-history>.

1 and (4) design and operate a system to identify suspicious orders of controlled  
2 substances, halt such unlawful sales, and report them to the DEA.

3 619. The closed-system created by the CSA, and the establishment of  
4 quotas, was specifically intended to reduce or eliminate the diversion of Schedule  
5 II substances like opioids from “legitimate channels of trade” to the illicit market  
6 by controlling the “quantities of the basic ingredients needed for the manufacture  
7 of [controlled substances].”<sup>441</sup>

8 620. Finding it impossible to legally achieve their ever increasing sales  
9 ambitions, members of the Opioid Diversion Enterprise (defined below) engaged  
10 in the common purpose of fraudulently increasing the quotas that governed the  
11 manufacture and distribution of their prescription opioids. The RICO Diversion  
12 Defendants formed and pursued their common purpose through the many personal  
13 interactions that they had, confidentially, in organizations like the Pain Care  
14 Forum and the Healthcare Distribution Alliance.

15 621. The RICO Diversion Defendants’ common purpose and fraudulent  
16 scheme to unlawfully increase the DEA quotas violated the RICO Act in two  
17 ways. First, the RICO Diversion Defendants violated the RICO Act because they  
18 engaged in the felonious manufacture, buying selling, or otherwise dealing in  
19 controlled substances that are punishable by law in the United States.  
20 Specifically, the RICO Diversion Defendants “furnish[ed] false or fraudulent  
21 material information in, or omit[ted] material information from, applications,  
22 reports, records, and other document required to be made, kept, and filed under 21  
23 U.S.C. §§ 801, et seq.”, in violation of 21 U.S.C. § 843(b), which is a felony.  
24 Second, the RICO Diversion Defendants violated the RICO Act by engaging in  
25

26 <sup>441</sup> 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi  
27 before the Caucus on International Narcotics Control, United States Senate, May 5,  
28 2015 (available at [https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\\_0.pdf](https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf)).

1 mail and wire fraud. The RICO Diversion Defendants common purpose and  
2 fraudulent scheme was intended to, and did, utilize interstate mail and wire  
3 facilities for the commission of their fraud in violation 18 U.S.C. §§ 1341 (mail  
4 fraud) and 1343 (wire fraud).

5 622. The RICO Diversion Defendants' fraudulent scheme arises at the  
6 intersection between the quotas governing the RICO Diversion Defendants'  
7 prescription opioids and the RICO Diversion Defendants' duty to identify, report,  
8 and halt suspicious orders of controlled substances. The RICO Diversion  
9 Defendants' formed an enterprise with the intent to fraudulently increase the  
10 quotas for prescription opioids by refusing to identify, report and halt suspicious  
11 orders, thereby omitting both the fact and the RICO Diversion Defendants'  
12 knowledge of widespread diversion of prescription opioids into illegitimate  
13 channels.

14 623. The RICO Diversion Defendants engaged in systematic and  
15 fraudulent acts as part of the Opioid Diversion Enterprise, that furnished false or  
16 fraudulent material information in, and omitted material information from their  
17 applications, reports, records and other documents that the RICO Defendants were  
18 required to make, keep and/or file. Furthermore, the RICO Diversion Defendants  
19 engaged in systematic and fraudulent acts as part of the Opioid Diversion  
20 Enterprise that were intended to and actually did utilize the mail and wire facilities  
21 of the United States and California, including refusing to maintain effective  
22 controls against diversion of their drugs, to design and operate a system to identify  
23 suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to  
24 notify the DEA of suspicious orders.<sup>442</sup>

25 624. Through the RICO Diversion Defendants' scheme, members of the  
26 Opioid Diversion Enterprise repeatedly requested increases of the quotas  
27

28 <sup>442</sup> 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

1 governing the manufacture, sale and distribution of prescription opioids,  
2 misrepresented that they were complying with their duties under the CSA,  
3 furnished false or fraudulent material information in, and omitted material  
4 information from their applications, reports, records and other documents,  
5 engaged in unlawful sales of painkillers that resulted in diversion of controlled  
6 substances through suspicious orders, and refused to identify or report suspicious  
7 orders of controlled substances sales to the DEA.<sup>443</sup> Defendants' refusal to report  
8 suspicious orders resulted in artificial and illegal increases in the annual  
9 production quotas for opioids allowed by the DEA. The end result of the RICO  
10 Diversion Defendants' fraudulent scheme and common purpose was continually  
11 increasing quotas that generated obscene profits and, in turn, fueled an opioid  
12 epidemic.

13         625. The RICO Diversion Defendants' illegal scheme was hatched by an  
14 enterprise between the Manufacturer Defendants and the Distributor Defendants,  
15 and executed in perfect harmony by each of them. In particular, each of the RICO  
16 Diversion Defendants were associated with, and conducted or participated in, the  
17 affairs of the Opioid Diversion Enterprise, whose common purpose was  
18 fraudulently increase the quotas governing the manufacture and sale of  
19 prescription opioids.

20         626. The success of the RICO Diversion Defendants' scheme allowed  
21 them to unlawfully increase and/or maintain high production quotas and, as a  
22 direct result, allowed them to make billions from the unlawful sale and diversion  
23 of opioids.

24         627. Simultaneously, the opioid epidemic created by the RICO Diversion  
25 Defendants' actions caused The County's multi-million dollar injuries. The  
26 County's injuries were and is a reasonably foreseeable consequence of the  
27

28 <sup>443</sup> 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

1 prescription opioid addiction epidemic that the RICO Diversion Defendants  
 2 created by fraudulently increasing quotas, misrepresenting their compliance with  
 3 their duties under the CSA, and allowing the widespread diversion of legally  
 4 produced prescription opioids into the illicit market. As explained in detail below,  
 5 the RICO Diversion Defendants' misconduct violated Section 1962(c) and the  
 6 County is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

7 **A. THE OPIOID DIVERSION ENTERPRISE.**

8 628. Recognizing that there is a need for greater scrutiny over controlled  
 9 substances due to their potential for abuse and danger to public health and safety,  
 10 the United States Congress enacted the Controlled Substances Act in 1970.<sup>444</sup> The  
 11 CSA and its implementing regulations created a closed-system of distribution for  
 12 all controlled substances and listed chemicals.<sup>445</sup> Congress specifically designed  
 13 the closed chain of distribution to prevent the diversion of legally produced  
 14 controlled substances into the illicit market.<sup>446</sup> Congress was concerned with the  
 15 diversion of drugs out of legitimate channels of distribution and acted to halt the  
 16 "widespread diversion of [controlled substances] out of legitimate channels into  
 17 the illegal market."<sup>447</sup> Moreover, the closed-system was specifically designed to  
 18 ensure that there are multiple ways of identifying and preventing diversion  
 19 through active participation by registrants within the drug delivery chain.<sup>448</sup> All  
 20

21  
 22 <sup>444</sup> Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr.,*  
*Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10,  
 23 2012).

24 <sup>445</sup> See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

25 <sup>446</sup> *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§  
 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept.  
 10, 1970).

26 <sup>447</sup> See Testimony of Joseph T. Rannazzisi before the Caucus on International  
 27 Narcotics Control, United States Senate, May 5, 2015 (available at  
[https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\\_0.pdf](https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf)).

28 <sup>448</sup> See Statement of Joseph T. Rannazzisi before the Caucus on International  
 Narcotics Control United States Senate, July 18, 2012 (available at



1 registrants -- manufacturers and distributors alike -- must adhere to the specific  
 2 security, recordkeeping, monitoring and reporting requirements that are designed  
 3 to identify or prevent diversion.<sup>449</sup> When registrants at any level fail to fulfill their  
 4 obligations, the necessary checks and balances collapse.<sup>450</sup> The result is the  
 5 scourge of addiction that has occurred

6 629. Central to the closed-system created by the CSA was the directive  
 7 that the DEA determine quotas of each basic class of Schedule I and II controlled  
 8 substances each year. The quota system was intended to reduce or eliminate  
 9 diversion from “legitimate channels of trade” by controlling the “quantities of the  
 10 basic ingredients needed for the manufacture of [controlled substances], and the  
 11 requirement of order forms for all transfers of these drugs.”<sup>451</sup> When evaluating  
 12 production quotas, the DEA was instructed to consider the following information:

- 13 a. Information provided by the Department of Health and Human Services;
- 14 b. Total net disposal of the basic class by all manufacturers;
- 15 c. Trends in the national rate of disposal of the basic class;
- 16 d. An applicant’s production cycle and current inventory position;
- 17 e. Total actual or estimated inventories of the class and of all substances  
 18 manufactured from the class and trends in inventory accumulation; and
- 19 f. Other factors such as: changes in the currently accepted medical use of  
 20 substances manufactured for a basic class; the economic and physical  
 21

22  
 23 <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

24 <sup>449</sup> Id.

25 <sup>450</sup> Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

26 <sup>451</sup> 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi  
 27 before the Caucus on International Narcotics Control, United States Senate, May 5,  
 28 2015 (available at [https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\\_0.pdf](https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf)).

1 availability of raw materials; yield and sustainability issues; potential  
 2 disruptions to production; and unforeseen emergencies.<sup>452</sup>

3 630. It is unlawful for a registrant to manufacture a controlled substance in  
 4 Schedule II, like prescription opioids, that is (1) not expressly authorized by its  
 5 registration and by a quota assigned to it by DEA, or (2) in excess of a quota  
 6 assigned to it by the DEA.<sup>453</sup>

7 631. At all relevant times, the RICO Diversion Defendants operated as an  
 8 association-in-fact enterprise formed for the purpose of unlawfully increasing  
 9 sales, revenues and profits by fraudulently increasing the quotas set by the DEA  
 10 that would allow them to collectively benefit from a greater pool of prescription  
 11 opioids to manufacture and distribute. In support of this common purpose and  
 12 fraudulent scheme, the RICO Diversion Defendants jointly agreed to disregard  
 13 their statutory duties to identify, investigate, halt and report suspicious orders of  
 14 opioids and diversion of their drugs into the illicit market so that those orders  
 15 would not result in a decrease, or prevent an increase in, the necessary quotas.  
 16 The RICO Diversion Defendants conducted their pattern of racketeering activity  
 17 in this jurisdiction and throughout the United States through this enterprise.

18 632. The opioid epidemic has its origins in the mid-1990s when, between  
 19 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone  
 20 increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription  
 21 opioids were sold in the United States to medicate every adult in the country with  
 22 a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.<sup>454</sup> On  
 23

24 <sup>452</sup> See Testimony of Joseph T. Rannazzisi before the Caucus on International  
 25 Narcotics Control, United State Senate, May 5, 2015 (available at  
 26 [https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\\_0.pdf](https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf)).

27 <sup>453</sup> *Id.* (citing 21 U.S.C. 842(b)).

28 <sup>454</sup> Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-  
 urban differences in nonmedical prescription opioid use and abuse in the United  
 States. *Am J Public Health.* 2014;104(2):e52-9.

1 information and belief, the Opioid Diversion Enterprise has been ongoing for at  
 2 least the last decade.<sup>455</sup>

3 633. The Opioid Diversion Enterprise was and is a shockingly successful  
 4 endeavor. The Opioid Diversion Enterprise has been conducting business  
 5 uninterrupted since its genesis. However, it was not until recently that federal and  
 6 state regulators finally began to unravel the extent of the enterprise and the toll  
 7 that it exacted on the American public.

8 634. At all relevant times, the Opioid Diversion Enterprise: (a) had an  
 9 existence separate and distinct from each RICO Diversion Defendant; (b) was  
 10 separate and distinct from the pattern of racketeering in which the RICO  
 11 Diversion Defendants engaged; (c) was an ongoing and continuing organization  
 12 consisting of legal entities, including each of the RICO Diversion Defendants; (d)  
 13 was characterized by interpersonal relationships among the RICO Diversion  
 14 Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose;  
 15 and (f) functioned as a continuing unit.. Each member of the Opioid Diversion  
 16 Enterprise participated in the conduct of the enterprise, including patterns of  
 17 racketeering activity, and shared in the astounding growth of profits supplied by  
 18 fraudulently inflating opioid quotas and resulting sales.

19 635. The Opioid Diversion Enterprise also engaged in efforts to constrain  
 20 the DEA's authority to hold the RICO Diversion Defendants liable for  
 21 disregarding their duty to prevent diversion. Members of the Pain Care Forum  
 22 (described in greater detail below) and the Healthcare Distribution Alliance  
 23 lobbied for the passage of legislation to weaken the DEA's enforcement authority.  
 24 To this end, the Ensuring Patient Access and Effective Drug Enforcement Act  
 25 significantly reduced the DEA's ability to issue orders to show cause and to  
 26

27 <sup>455</sup> Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug  
 28 epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),  
[https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic)  
[shaped-policy-amid-drug-epidemic](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic).

suspend and/or revoke registrations.<sup>456</sup> The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Upon information and belief, the Pain Care Forum and its members and HDA, poured millions into such efforts.

636. The RICO Diversion Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to profit from the unlawful sale of prescription opioids by increasing the quotas governing the manufacture and sale of these controlled substances. In order to achieve that goal, the RICO Diversion Defendants knowingly allowed suspicious orders of controlled substances to occur unhindered while millions of opioid doses diverted into illegal markets. The end result of this strategy was exactly as the RICO Diversion Defendants intended – artificially increased quotas for the manufacture and distribution of opioids, all of which resulted in a National opioid epidemic.

637. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution,

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<sup>456</sup> See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9\\_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, [https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf\\_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

1 and shipment of prescription opioids throughout the United States, and the  
2 corresponding payment and/or receipt of money from such interstate sales.

3 638. Within the Opioid Diversion Enterprise, there were interpersonal  
4 relationships and common communication by which the RICO Diversion  
5 Defendants shared information on a regular basis. These interpersonal  
6 relationships also formed the organization of the Opioid Diversion Enterprise.  
7 The Opioid Diversion Enterprise used their interpersonal relationships and  
8 communication network for the purpose of conducting the enterprise through a  
9 pattern of racketeering activity.

10 639. Each of the RICO Diversion Defendants had systematic links to each  
11 other through joint participation in trade industry organizations, contractual  
12 relationships and continuing coordination of activities. The RICO Diversion  
13 Defendants participated in the operation and management of the Opioid Diversion  
14 Enterprise by directing its affairs, as described herein. While the RICO Diversion  
15 Defendants participated in, and are members of, the enterprise, they each have a  
16 separate existence from the enterprise, including distinct legal statuses, different  
17 offices and roles, bank accounts, officers, directors, employees, individual  
18 personhood, reporting requirements, and financial statements.

19 640. The RICO Diversion Defendants exerted substantial control over the  
20 Opioid Diversion Enterprise through their membership in the Pain Care Forum,  
21 the HDA, and through their contractual relationships.

22 641. The Pain Care Forum (“PCF”) has been described as a coalition of  
23 drug makers, trade groups and dozens of non-profit organizations supported by  
24 industry funding. The PCF recently became a national news story when it was  
25 discovered that lobbyists for members of the PCF quietly shaped federal and state  
26 policies regarding the use of prescription opioids for more than a decade.

27 642. The Center for Public Integrity and The Associated Press obtained  
28 “internal documents shed[ding] new light on how drug makers and their allies

1 shaped the national response to the ongoing wave of prescription opioid abuse.”<sup>457</sup>  
 2 Specifically, PCF members spent over \$740 million lobbying in the nation’s  
 3 capital and in all 50 statehouses on an array of issues, including opioid-related  
 4 measures.<sup>458</sup>

5 643. Not surprisingly, each of the RICO Diversion Defendants who stood  
 6 to profit from expanded prescription opioid use is a member of and/or participant  
 7 in the PCF.<sup>459</sup> In 2012, membership and participating organizations included the  
 8 HDA (of which all RICO Defendants are members), Endo, Purdue, Actavis (i.e.,  
 9 Allergan), and Teva (the parent company of Cephalon).<sup>460</sup> Each of the  
 10 Manufacturer Defendants worked together through the PCF to advance the  
 11 interests of the enterprise. But, the Manufacturer Defendants were not alone. The  
 12 Distributor Defendants actively participated, and continue to participate in the  
 13 PCF, at a minimum, through their trade organization, the HDA.<sup>461</sup> Upon  
 14 information and belief, the Distributor Defendants participated directly in the PCF  
 15 as well.

16 644. Additionally, the HDA – or Healthcare Distribution Alliance – led to  
 17 the formation of interpersonal relationships and an organization between the  
 18

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19 <sup>457</sup> Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug  
 20 epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),  
 21 [https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic)  
 22 [shaped-policy-amid-drug-epidemic](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic) (emphasis added).

23 <sup>458</sup> *Id.*

24 <sup>459</sup> PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011),  
 25 [https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf)  
 26 [Meetings-Schedule-amp.pdf](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf)

27 <sup>460</sup> *Id.* Upon information and belief, Mallinckrodt became an active member of the  
 28 PCF sometime after 2012.

<sup>461</sup> *Id.* The Executive Committee of the HDA (formerly the HDMA) currently  
 includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health,  
 Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source  
 for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for  
 McKesson Corporation. Executive Committee, Healthcare Distribution Alliance  
 (accessed on September 14, 2017),  
<https://www.healthcaredistribution.org/about/executive-committee>.



1 RICO Diversion Defendants. Although the entire HDA membership directory is  
 2 private, the HDA website confirms that each of the Distributor Defendants and the  
 3 Manufacturer Defendants named in the Complaint, including Actavis (i.e.,  
 4 Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the  
 5 HDA.<sup>462</sup> Additionally, the HDA and each of the Distributor Defendants, eagerly  
 6 sought the active membership and participation of the Manufacturer Defendants  
 7 by advocating for the many benefits of members, including “**strengthening . . .**  
 8 **alliances.**”<sup>463</sup>

9 645. Beyond strengthening alliances, the benefits of HDA membership  
 10 included the ability to, among other things, “network one on one with  
 11 manufacturer executives at HDA’s members-only Business and Leadership  
 12 Conference,” “networking with HDA wholesale distributor members,”  
 13 “opportunities to host and sponsor HDA Board of Directors events,” “participate  
 14 on HDA committees, task forces and working groups with peers and trading  
 15 partners,” and “make connections.”<sup>464</sup> Clearly, the HDA and the Distributor  
 16 Defendants believed that membership in the HDA was an opportunity to create  
 17 interpersonal and ongoing organizational relationships and “alliances” between  
 18 the Manufacturers and Defendants.

19 646. The application for manufacturer membership in the HDA further  
 20 indicates the level of connection between the RICO Defendants and the level of  
 21 insight that they had into each other’s businesses.<sup>465</sup> For example, the  
 22

23 <sup>462</sup> Manufacturer Membership, Healthcare Distribution Alliance, (accessed on  
 24 September 14, 2017),  
<https://www.healthcaredistribution.org/about/membership/manufacturer>.

25 <sup>463</sup> Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed  
 26 on September 14, 2017),  
<https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

27 <sup>464</sup> *Id.*

28 <sup>465</sup> Manufacturer Membership Application, Healthcare Distribution Alliance,  
 (accessed on September 14, 2017),

1 manufacturer membership application must be signed by a “senior company  
2 executive,” and it requests that the manufacturer applicant identify a key contact  
3 and any additional contacts from within its company.

4 647. The HDA application also requests that the manufacturer identify its  
5 current distribution information, including the facility name and contact  
6 information.

7 648. And, Manufacturer Members were asked to identify their “most  
8 recent year end net sales” through wholesale distributors, including the Distributor  
9 Defendants AmerisourceBergen, Cardinal Health, and McKesson and their  
10 subsidiaries.

11 649. The closed meetings of the HDA’s councils, committees, task forces  
12 and working groups provided the Manufacturer and Distributor Defendants with  
13 the opportunity to work closely together, confidentially, to develop and further the  
14 common purpose and interests of the enterprise.

15 650. The HDA also offers a multitude of conferences, including annual  
16 business and leadership conferences. The HDA, and the Distributor Defendants  
17 advertise these conferences to the Manufacturer Defendants as an opportunity to  
18 “bring together high-level executives, thought leaders and influential managers . .  
19 . to hold strategic business discussions on the most pressing industry issues.”<sup>466</sup>  
20 The conferences also gave the Manufacturer and Distributor Defendants  
21 “unmatched opportunities to network with [their] peers and trading partners at all  
22 levels of the healthcare distribution industry.”<sup>467</sup> The HDA and its conferences  
23

24 [https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturing-](https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturing-membership-application.ashx?la=en)  
25 [membership-application.ashx?la=en](https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturing-membership-application.ashx?la=en).

26 <sup>466</sup> Business and Leadership Conference – Information for Manufacturers,  
27 Healthcare Distribution Alliance[https://www.healthcaredistribution.org/events/2015-business-and-](https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers)  
28 [leadership-conference/blc-for-manufacturers](https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers) (last accessed on September 14,  
2017).

<sup>467</sup> *Id.*

1 were significant opportunities for the Manufacturer and Distributor Defendants to  
 2 interact at a high-level of leadership. It is clear that the Manufacturer Defendants  
 3 embraced this opportunity by attending and sponsoring these events.<sup>468</sup>

4 651. Third, the RICO Diversion Defendants maintained their interpersonal  
 5 relationships by working together, through contractual chargeback arrangements,  
 6 to exchanging sales information and drive the unlawful sales of their opioids. To  
 7 this end, the Manufacturer Defendants engaged in an industry-wide practice of  
 8 paying rebates to the Distributor Defendants for sales of prescription opioids.<sup>469</sup>

9 652. For example, the *Washington Post* reported that “[o]n Aug. 23, 2011,  
 10 DEA supervisors met with Mallinckrodt executives at the agency’s headquarters  
 11 in Arlington, Va., the day a rare 5.8-magnitude earthquake hit the Washington  
 12 region. People involved in the case still call the gathering ‘the earthquake  
 13 meeting.’ DEA officials showed the company the remarkable amounts of its  
 14 oxycodone going to distributors and the number of arrests being made for  
 15 oxycodone possession and distribution on the street, according to one participant  
 16 in the meeting who also spoke on the condition of anonymity because the case is  
 17 pending.”<sup>470</sup>

18  
 19 <sup>468</sup> 2015 Distribution Management Conference and Expo, Healthcare Distribution  
 20 Alliance, [https://www.healthcaredistribution.org/events/2015-distribution-](https://www.healthcaredistribution.org/events/2015-distribution-management-conference)  
 management-conference (last accessed on September 14, 2017).

21 <sup>469</sup> Lenny Bernstein & Scott Higham, The government’s struggle to hold opioid  
 22 manufacturers accountable, The Washington Post, (April 2, 2017),  
 23 [https://www.washingtonpost.com/graphics/investigations/dea-](https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356)  
 mallinckrodt/?utm\_term=.b24cc81cc356; *see also*, Letter from Sen. Claire  
 24 McCaskill, (July 27, 2017),  
[https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-](https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png)  
 25 letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017),  
[https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-](https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png)  
 26 letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017),  
<https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets,  
 Purdue Pharma, (accessed on September 14, 2017),  
<http://www.purduepharma.com/payers/managed-markets/>.

27 <sup>470</sup> [https://www.washingtonpost.com/graphics/investigations/dea-](https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.f336835fd5da)  
 28 mallinckrodt/?utm\_term=.f336835fd5da

1           653. “Three weeks after the Aug. 23 meeting, Mallinckrodt notified 43 of  
2 its distributors that they would no longer receive rebates from the company if they  
3 continued to supply certain pharmacies whose orders appeared to be  
4 suspicious.”<sup>471</sup>

5           654. “On Nov. 30, 2011, the DEA served a subpoena on Mallinckrodt,  
6 demanding documents related to its suspicious-order-monitoring program,  
7 according to the company’s filings with the Securities and Exchange Commission.  
8 The subpoena brought a windfall of information. The DEA gained access to data  
9 from Mallinckrodt’s rebate or ‘chargeback’ program, an industry-wide practice  
10 that provides reimbursements to wholesale distributors. That information and  
11 other records showed where Mallinckrodt’s oxycodone was going — from the  
12 company to its network of distributors to retailers down the chain.”<sup>472</sup>

13           655. In addition, the Distributor Defendants and Manufacturer Defendants  
14 participated, through the HDA, in Webinars and other meetings designed to  
15 exchange detailed information regarding their prescription opioid sales, including  
16 purchase orders, acknowledgements, ship notices, and invoices.<sup>473</sup> For example,  
17 on April 27, 2011, the HDA offered a Webinar to “accurately and effectively  
18 exchange business transactions between distributors and manufacturers...”:  
19  
20  
21  
22  
23  
24  
25

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26 <sup>471</sup> Id.

27 <sup>472</sup> Id.

28 <sup>473</sup> Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017),  
<https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

## Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set



(Webinar held: April 27, 2011) Using EDI to accurately and efficiently exchange business transactions (i.e., purchase orders, acknowledgements, ship notices, invoices, etc.) between distributors and manufacturers in the healthcare supply chain is critical. The development and use of voluntary guidelines for specific EDI standards provide industry

trading partners with a means to effectively convey the necessary information.

Hear updates on HDMA's Order-to-Cash Guidelines for Electronic Data Interchange (EDI) in the Healthcare Product Supply Chain, including the 810 Invoice; 850 Purchase Order; 855 Purchase Order Acknowledgement; and the 856 Ship Notice/Manifest.

656. On information and belief, the Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

657. And, through the HDA, Manufacturer Members were asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants as follows:

Company	Most Recent Year End Net Sales
Henry Schein, Inc.	
Henry Schein Distribution Centers (7)	
Hospital Pharmaceutical Consulting (1)	
KeySource Medical, Inc. (1)	
Louisiana Wholesale Drug Co. Inc. (1)	
McKesson Corporation (71)	
McKesson Supply Solutions (25)	
McKesson Canada (12)	
McKesson Corporation (4)	
McKesson Specialty Health (1)	
McKesson Strategic Redistribution Center (1)	
McKesson Medical Surgical (1)	
Physician Sales & Service (PSS) (25)	
US Oncology (1)	
DeVetoria Healthcare, Inc. PR (1)	
Miami-Luken, Inc. (1)	
Morris & Dickson Co., LLC (1)	
Mutual Wholesale Drug Co. (1)	
PBA Health (1)	
Prescription Supply, Inc. (1)	
Prodigy Health Supplier Corporation (1)	
Quality Care Products, LLC (1)	
RDC (3)	
R&S Northeast LLC (2)	
Richie Pharmacal Co., LLC (1)	
Seacoast Medical LLC (1)	
Smith Drug Company, Div. J.M. Smith Corporation (4)	
Burlington Drug Company, Inc. (1)	
Smith Drug Company, Div. J.M. Smith Corporation (3)	
Top Rx (4)	
Value Drug Company (1)	
VaxServe (1)	
<b>TOTAL SALES (millions)</b>	<b>\$ (1)</b>

1           658. The contractual relationships among the RICO Defendants also  
2 include vault security programs. The RICO Diversion Defendants are required to  
3 maintain certain security protocols and storage facilities for the manufacture and  
4 distribution of their opiates. Upon information and belief, the manufacturers  
5 negotiated agreements whereby the Manufacturers installed security vaults for  
6 Distributors in exchange for agreements to maintain minimum sales performance  
7 thresholds. Upon information and belief, these agreements were used by the  
8 RICO Diversion Defendants as a tool to violate their reporting and diversion  
9 duties in order to reach the required sales requirements.

10           659. Taken together, the interaction and length of the relationships  
11 between and among the Manufacturer and Distributor Defendants reflects a deep  
12 level of interaction and cooperation between two groups in a tightly knit industry.  
13 The Manufacturer and Distributor Defendants were not two separate groups  
14 operating in isolation or two groups forced to work together in a closed system.  
15 The RICO Diversion Defendants operated together as a united entity, working  
16 together on multiple fronts, to engage in the unlawful sale of prescription opioids.  
17 The HDA and the Pain Care Forum are but two examples of the overlapping  
18 relationships, and concerted joint efforts to accomplish common goals and  
19 demonstrates that the leaders of each of the RICO Diversion Defendants were in  
20 communication and cooperation.

21           660. Alternatively, the RICO Diversion Defendants were members of a  
22 legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which  
23 the RICO Diversion Defendants conducted their pattern of racketeering activity in  
24 this jurisdiction and throughout the United States. As alleged, the Healthcare  
25 Distribution Alliance (the “HDA”)<sup>474</sup> is a distinct legal entity that satisfies the  
26

27 \_\_\_\_\_  
28 <sup>474</sup> Health Distribution Alliance, History, Health Distribution Alliance, (last  
accessed on September 15, 2017),  
<https://www.healthcaredistribution.org/about/hda-history>.



1 definition of a RICO enterprise because it is a corporation formed under the laws  
2 of the District of Columbia, doing business in Virginia. As such, the HDA  
3 qualifies as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4).

4 661. On information and belief, each of the RICO Diversion Defendants is  
5 a member, participant, and/or sponsor of the HDA, and has been since at least  
6 2006, and utilized the HDA to conduct the Opioid Diversion Enterprise and to  
7 engage in the pattern of racketeering activity that gives rise to the Count.

8 662. Each of the RICO Diversion Defendants is a legal entity separate and  
9 distinct from the HDA. Additionally, the HDA serves the interests of distributors  
10 and manufacturers beyond the RICO Diversion Defendants. Therefore, the HDA  
11 exists separately from the Opioid Diversion Enterprise, and each of the RICO  
12 Diversion Defendants exists separately from the HDA. Therefore, the HDA may  
13 serve as a RICO enterprise.

14 **B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.**

15 663. During the time period alleged in this Complaint, the RICO  
16 Diversion Defendants exerted control over, conducted and/or participated in the  
17 Opioid Diversion Enterprise by fraudulently claiming that they were complying  
18 with their duties under the CSA to identify, investigate and report suspicious  
19 orders of opioids in order to prevent diversion of those highly addictive substances  
20 into the illicit market, and to halt such unlawful sales, so as to increase production  
21 quotas and generate unlawful profits, as follows:

22 664. Defendants disseminated false and misleading statements to state and  
23 federal regulators claiming that (1) the quotas for prescription opioids should be  
24 increased, (2) they were complying with their obligations to maintain effective  
25 controls against diversion of their prescription opioids, (3) they were complying  
26 with their obligations to design and operate a system to disclose to the registrant  
27 suspicious orders of their prescription opioids, (4) they were complying with their  
28 obligation to notify the DEA of any suspicious orders or diversion of their

1 prescription opioids and (5) they did not have the capability to identify suspicious  
 2 orders of controlled substances despite their possession of national, regional, state,  
 3 and local prescriber- and patient-level data that allowed them to track prescribing  
 4 patterns over time, which the Defendants obtained from data companies, including  
 5 but not limited to: IMS Health, QuintilesIMS, Iqvia, Pharmaceutical Data  
 6 Services, Source Healthcare Analytics, NDS Health Information Services,  
 7 Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or  
 8 PRA Health Science, and all of their predecessors or successors in interest (the  
 9 “Data Vendors”).

10 665. The RICO Diversion Defendants applied political and other pressure  
 11 on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of  
 12 prescription opioids and lobbied Congress to strip the DEA of its ability to  
 13 immediately suspend registrations pending investigation by passing the “Ensuring  
 14 Patient Access and Effective Drug Enforcement Act.”<sup>475</sup>

15 666. The Distributor Defendants developed “know your customer”  
 16 questionnaires and files. This information, compiled pursuant to comments from  
 17 the DEA in 2006 and 2007 was intended to help the RICO Diversion Defendants  
 18 identify suspicious orders or customers who were likely to divert prescription  
 19

20  
 21 <sup>475</sup> See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical  
 22 Commerce, (June 13, 2016, updated July 6, 2016),  
 23 [http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/)  
 24 [distribution-alliance/](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/); Lenny Bernstein & Scott Higham, *Investigation: The DEA*  
 25 *Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post,  
 26 Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html)  
 27 [enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html)  
 28 [7f71-11e6-8d13-d7c704ef9fd9\\_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html); Lenny Bernstein & Scott Higham,  
*Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown*  
*Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017,  
[https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html)  
[of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html)  
[a05d3c21f7cf\\_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA Agent: “We Had no Leadership” in WV*  
*Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017,  
[http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-)  
[in-wv-amid-flood-of-pain-pills-.](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-)

1 opioids.<sup>476</sup> On information and belief, the “know your customer” questionnaires  
 2 informed the RICO Diversion Defendants of the number of pills that the  
 3 pharmacies sold, how many non-controlled substances are sold compared to  
 4 controlled substances, whether the pharmacy buys from other distributors, the  
 5 types of medical providers in the area, including pain clinics, general practitioners,  
 6 hospice facilities, cancer treatment facilities, among others, and these  
 7 questionnaires put the recipients on notice of suspicious orders.

8 667. The RICO Diversion Defendants purchased nationwide, regional,  
 9 state, and local prescriber- and patient-level data from the Data Vendors that  
 10 allowed them to track prescribing trends, identify suspicious orders, identify  
 11 patients who were doctor shopping, identify pill mills, etc. The Data Vendors’  
 12 information purchased by the RICO Diversion Defendants allowed them to view,  
 13 analyze, compute, and track their competitors sales, and to compare and analyze  
 14 market share information.<sup>477</sup>

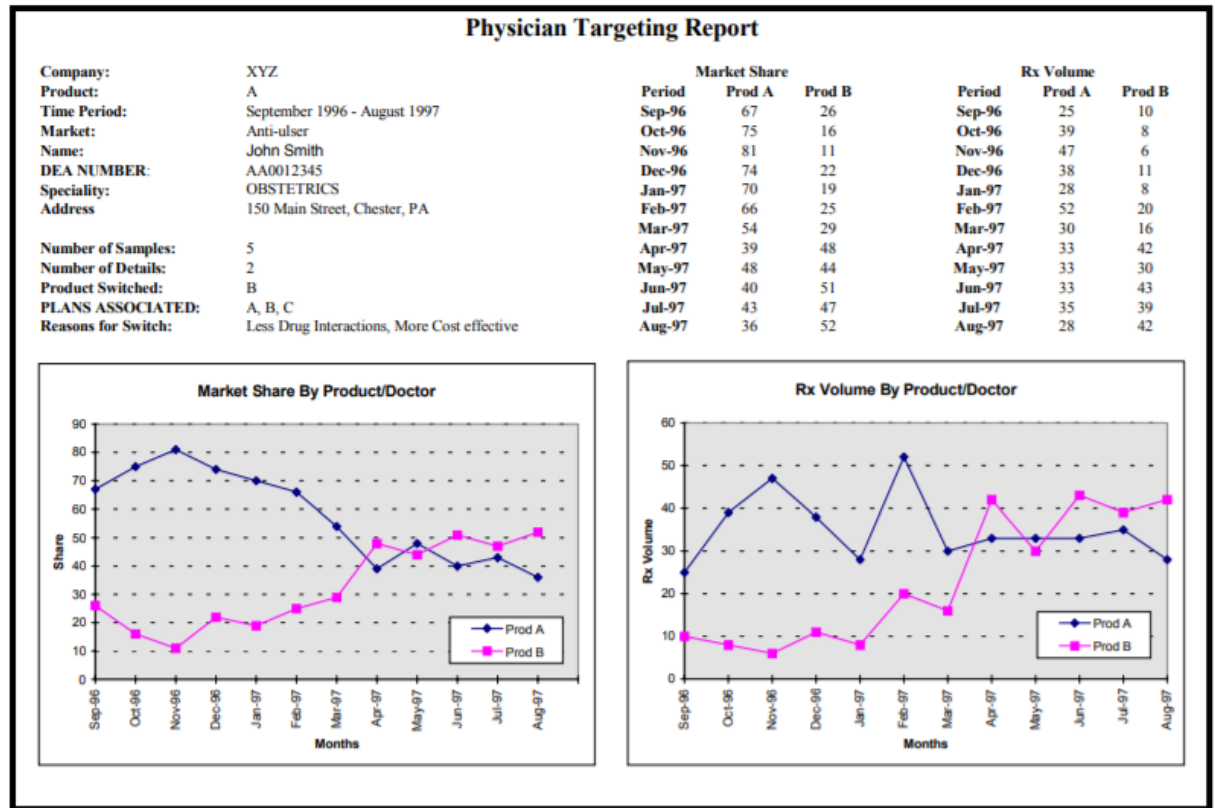
15 668. IMS, for example, IMS provided the RICO Diversion Defendants  
 16 with reports detailing prescriber behavior and the number of prescriptions written  
 17 between competing products.<sup>478</sup>

21 <sup>476</sup> Suggested Questions a Distributor should ask prior to shipping controlled  
 22 substances, Drug Enforcement Administration (available at  
 23 [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_industry/14th\\_pharm/levinl\\_ques](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf)  
 24 [.pdf](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf)); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production  
Diversion: Beyond the PDMA, Purdue Pharma and McGuireWoods LLC,  
 (available at [https://www.mcguirewoods.com/news-](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf)  
[resources/publications/lifesciences/product\\_diversion\\_beyond\\_pdma.pdf](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf)).

25 <sup>477</sup> A Verispan representative testified that the RICO Defendants use the  
 26 prescribing information to “drive market share.” *Sorrell v. IMS Health Inc.*, 2011  
 WL 661712, \*9-10 (Feb. 22, 2011).

27 <sup>478</sup> Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned*  
 28 *a Mountain of Data into a Few Information-rich Molehills*, (accessed on February  
 15, 2018),  
[http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&typ](http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf)  
 e=pdf, Figure 2 at p.3.

Figure 2:



669. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the RICO Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.<sup>479</sup>

<sup>479</sup> *Sorrell v. IMS Health Inc.*, 2011 WL 705207, \*467-471 (Feb. 22, 2011).

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1. The Prescriber Roster shows Prescriber demographics, prescribing information and indicator arrows

Territory : 1102 Prescriber				Weekly Prescriber TR			
	Trend	Specialty	Product	WEEK Feb-03-06	WEEK Jan-27-06	WEEK Jan-20-06	WEEK Jan-13-06
Territory : 1102 – TOTAL			PRODUCT A	46	64	58	88
			PRODUCT B	292	253	247	278
			PRODUCT C	55	56	56	58
			PRODUCT D	36	28	34	33
			PRODUCT E	7	9	2	9
			PRODUCT F	1	3	5	0
Doctor A		IM	PRODUCT A	4	1	1	1
			PRODUCT B	2	2	2	3
			PRODUCT C	0	2	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0
Doctor B		GE	PRODUCT A	3	1	1	2
			PRODUCT B	5	4	7	2
			PRODUCT C	0	1	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	1	0	1
			PRODUCT F	0	0	0	0
Doctor C		GE	PRODUCT A	3	1	2	0
			PRODUCT B	4	5	0	3
			PRODUCT C	0	1	1	0
			PRODUCT D	0	1	0	2
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0

\* \* \*



3. Territory Summary Report shows Prescriber Roster information aggregated at a territory level

#### Territory Summary

Name	Spec	Zip	Product A NRX	Product A MM Share	Product A Rank	Market NRX	Market Rank
ABNEY, RAY C.	P	05302	6	10.7%	43	56	38
ALLISTER, ROBERT	P	03820	6	18.8%	43	32	63
ALTMAN, LEE S.	P	01655	34	14.0%	3	247	3
BALLARD, HARLOW	P	05801	0	0.0%	93	8	96
BARNEY, CHRISTINE A.	P	03766	6	26.1%	43	23	85
BARTON, GAIL	P	03755	13	32.5%	18	40	50
BERNSTEIN, RICHARD A.	P	05401	0	0.0%	93	14	94
BOHNERI, MICHAEL	P	03060	3	4.5%	73	66	29
BOSTIC, JEFFERY O.	CHP	03079	5	10.9%	55	45	44
BREITHOLTZ, TIMOTHY	P	03870	13	34.2%	18	38	52
BROWN, KENNETH	P	03941	4	10.0%	61	40	50
BUCHANAN, KEVIN	P	05701	5	16.1%	55	31	70
CARMAN, MEGAN W.	P	03246	10	12.3%	28	81	18
CARSEN, MARJORIA	P	05701	6	18.2%	43	33	59
CATPANO-FRIEDMAN, LISA	P	05201	5	8.6%	43	70	25
CLARKE-RUBIN, LORNA	P	12901	8	24.2%	32	33	59
COHEN, DEVRA H.	CHP	03060	3	6.5%	73	46	44
COLE, STEPHEN A.	P	05101	5	13.2%	55	38	52
COTTON, PAUL G.	P	05401	13	28.3%	18	46	44
CUSI, PRISCILLA M.	P	03104	17	7.9%	14	215	5
DAVISON, MARTHA F.	P	03110	14	11.3%	16	124	8
DEJONG, JACOB	P	03067	0	0.0%	93	21	87
DELFAUSSE, PETER O.	P	03301	6	35.3%	43	17	90
DENNETT, DOUGLAS E.	CHP	05401	0	0.0%	93	33	59
DEPPE, SUSAN L.	P	05401	1	0.3%	87	300	2
DEVENDERRAO, T.	P	03060	7	9.6%	37	73	21

670. This information allowed the RICO Diversion Defendants to track and identify instances of, overprescribing.<sup>480</sup> In fact, one of the Data Venders' experts testified that a manufacturer of "narcotic analgesics" used the Data Venders' information to track, identify, report and halt suspicious orders of controlled substances.<sup>481</sup>

<sup>480</sup> See *Sorrell v. IMS Health Inc.*, 2011 WL 1449043, \*37-38 (March 24, 2011) (arguing that data had been used to "identify overuse of antibiotics in children," and "whether there is a wide use of anthrax prophylactic medicines after the scares happened in 2001."). The Data Vender Respondents also cited evidence from the trial court proving that "because analysis of PI data makes it possible to 'identify overuse of a pharmaceutical in specific conditions, the government employs the data to monitor usage of controlled substances.'" *Id.*

<sup>481</sup> *Id.* at \*38. Eugene "Mick" Kolassa testified as an expert on behalf of the Data Vender stating that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an



1 [455] Q. Besides marketing and promotion, are  
2 there any other uses for prescriber-identifiable data?

3 A. There's a number of other uses.

4 Q. And what are those?

5 A. The one that I was most impressed with  
6 was a firm that used it to identify – a firm that  
7 sells narcotic analgesics was able to use prescriber-  
8 identifiable information to identify physicians that  
9 seemed to be prescribing an inordinately high num-  
10 ber of prescriptions for their product and they would  
11 use that to notify the DEA and other authorities of  
12 potential problems.

13  
14 671. The RICO Diversion Defendants were, therefore, collectively aware  
15 of the suspicious orders that flowed daily from their manufacturing and  
16 distribution facilities.

17 672. The RICO Diversion Defendants refused to identify, investigate and  
18 report suspicious orders to the DEA when they became aware of the same despite  
19 their actual knowledge of drug diversion rings. The RICO Diversion Defendants  
20 refused to identify suspicious orders and diverted drugs despite the DEA issuing  
21 final decisions against the Distributor Defendants in 178 registrant actions  
22 between 2008 and 2012<sup>482</sup> and 117 recommended decision in registrant actions  
23 from The Office of Administrative Law Judges. These numbers include seventy-  
24 six (76) actions involving orders to show cause and forty-one (41) actions

25  
26 inordinately high number of prescriptions for their product.” *Id*; see also Joint  
27 Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at \*204 (Feb. 22, 2011).

28 <sup>482</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of  
Justice, *The Drug Enforcement Administration’s Adjudication of Registrant*  
*Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

1 involving immediate suspension orders – all for failure to report suspicious  
2 orders.<sup>483</sup>

3 673. Defendants’ scheme had a decision-making structure driven by the  
4 Manufacturer Defendants and corroborated by the Distributor Defendants. The  
5 Manufacturer Defendants worked together to control the State and Federal  
6 Government’s response to the manufacture and distribution of prescription opioids  
7 by increasing production quotas through a systematic refusal to maintain effective  
8 controls against diversion, and identify suspicious orders and report them to the  
9 DEA.

10 674. The RICO Diversion Defendants worked together to control the flow  
11 of information and influence state and federal governments and political  
12 candidates to pass legislation that was pro-opioid. The Manufacturer and  
13 Distributor Defendants did this through their participation in the PCF and HDA.

14 675. The RICO Diversion Defendants also worked together to ensure that  
15 the Aggregate Production Quotas, Individual Quotas and Procurement Quotas  
16 allowed by the DEA remained artificially high and ensured that suspicious orders  
17 were not reported to the DEA in order to ensure that the DEA had no basis for  
18 refusing to increase or decrease production quotas due to diversion. The RICO  
19 Diversion Defendants influenced the DEA production quotas in the following  
20 ways:

21 676. The scheme devised and implemented by the RICO Diversion  
22 Defendants amounted to a common course of conduct characterized by a refusal to  
23 maintain effective controls against diversion, and all designed and operated to  
24 ensure the continued unlawful sale of controlled substances.

25  
26  
27  
28 <sup>483</sup> Id.

1           **C.     PATTERN OF RACKETEERING ACTIVITY.**

2           677. The RICO Diversion Defendants conducted and participated in the  
3 conduct of the Opioid Diversion Enterprise through a pattern of racketeering  
4 activity as defined in 18 U.S.C. § 1961(1)(D), including ; the felonious  
5 manufacture, importation, receiving, concealment buying selling, or otherwise  
6 dealing in a controlled substance or listed chemical (as defined in section 102 of  
7 the Controlled Substance Act), punishable under any law of the United States; and  
8 18 U.S.C. 1961(1)(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18  
9 U.S.C. § 1343).

10                           **1. The RICO Defendants Manufactured, Sold and/or Dealt**  
11                           **in Controlled Substances and Their Actions Constitute**  
12                           **Crimes Punishable as Felonies.**

13           678. The RICO Diversion Defendants conducted and participated in the  
14 conduct of the affairs of the Opioid Diversion Enterprise through a pattern of  
15 racketeering activity as defined in 18 U.S.C. § 1961(1)(D) by the felonious  
16 manufacture, importation, receiving, concealment, buying, selling, or otherwise  
17 dealing in a controlled substance or listed chemical (as defined in section 102 of  
18 the Controlled Substance Act), punishable under any law of the United States.

19           679. The RICO Diversion Defendants committed crimes that are  
20 punishable as felonies under the laws of the United States. Specifically, 21 U.S.C.  
21 § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish  
22 false or fraudulent information in, or omit any material information from, any  
23 application, report, record or other document required to be made, kept or filed  
24 under this subchapter. A violation of section 843(a)(4) is punishable by up to four  
25 years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

26           680. Each of the RICO Diversion Defendants qualifies as a registrant  
27 under the CSA. Their status as registrants under the CSA requires that they  
28 maintain effective controls against diversion of controlled substances in schedule I

1 or II, design and operate a system to disclose to the registrant suspicious orders of  
2 controlled substances and inform the DEA of suspicious orders when discovered  
3 by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

4 681. The CSA and the Code of Federal Regulations, require the RICO  
5 Diversion Defendants to make reports to the DEA of any suspicious orders  
6 identified through the design and operation of their system to disclose suspicious  
7 orders. The failure to make reports as required by the CSA and Code of Federal  
8 Regulations amounts to a criminal violation of the statute.

9 682. The RICO Diversion Defendants knowingly and intentionally  
10 furnished false or fraudulent information in their reports to the DEA about  
11 suspicious orders, and/or omitted material information from reports, records and  
12 other document required to be filed with the DEA including the Manufacturer  
13 Defendants' applications for production quotas. Specifically, the RICO Diversion  
14 Defendants were aware of suspicious orders of prescription opioids and the  
15 diversion of their prescription opioids into the illicit market, and failed to report  
16 this information to the DEA in their mandatory reports and their applications for  
17 production quotas.

18 683. Upon information and belief, the foregoing examples reflect the  
19 RICO Diversion Defendants' pattern and practice of willfully and intentionally  
20 omitting information from their mandatory reports to the DEA as required by 21  
21 C.F.R. § 1301.74. The sheer volume of enforcement actions available in the  
22 public record against the Distributor Defendants supports this conclusion.<sup>484</sup> For  
23 example:

24 684. On April 24, 2007, the DEA issued an *Order to Show Cause and*  
25 *Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida  
26

27 <sup>484</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of  
28 Justice, *The Drug Enforcement Administration's Adjudication of Registrant*  
*Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

1 distribution center (“Orlando Facility”) alleging failure to maintain effective  
2 controls against diversion of controlled substances. On June 22, 2007,  
3 AmerisourceBergen entered into a settlement that resulted in the suspension of its  
4 DEA registration.

5 685. On November 28, 2007, the DEA issued an *Order to Show Cause*  
6 *and Immediate Suspension Order* against the Cardinal Health Auburn,  
7 Washington Distribution Center (“Auburn Facility”) for failure to maintain  
8 effective controls against diversion of hydrocodone.

9 686. On December 5, 2007, the DEA issued an *Order to Show Cause and*  
10 *Immediate Suspension Order* against the Cardinal Health Lakeland, Florida  
11 Distribution Center (“Lakeland Facility”) for failure to maintain effective controls  
12 against diversion of hydrocodone.

13 687. On December 7, 2007, the DEA issued an *Order to Show Cause and*  
14 *Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey  
15 Distribution Center (“Swedesboro Facility”) for failure to maintain effective  
16 controls against diversion of hydrocodone.

17 688. On January 30, 2008, the DEA issued an *Order to Show Cause and*  
18 *Immediate Suspension Order* against the Cardinal Health Stafford, Texas  
19 Distribution Center (“Stafford Facility”) for failure to maintain effective controls  
20 against diversion of hydrocodone.

21 689. On May 2, 2008, McKesson Corporation entered into an  
22 *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which  
23 provided that McKesson would “maintain a compliance program designed to  
24 detect and prevent the diversion of controlled substances, inform DEA of  
25 suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures  
26 established by its Controlled Substance Monitoring Program.”

27 690. On September 30, 2008, Cardinal Health entered into a *Settlement*  
28 *and Release Agreement and Administrative Memorandum of Agreement* with the

1 DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and  
2 Stafford Facility. The document also referenced allegations by the DEA that  
3 Cardinal failed to maintain effective controls against the diversion of controlled  
4 substances at its distribution facilities located in McDonough, Georgia  
5 (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver,  
6 Colorado (“Denver Facility”).

7 691. On February 2, 2012, the DEA issued an *Order to Show Cause and*  
8 *Immediate Suspension Order* against the Cardinal Health Lakeland, Florida  
9 Distribution Center (“Lakeland Facility”) for failure to maintain effective controls  
10 against diversion of oxycodone.

11 692. On May, 14, 2012, Cardinal Health entered into an Administrative  
12 Memorandum of Agreement with the DEA in which, among other things,  
13 Cardinal Health “admits that its due diligence efforts for some pharmacy  
14 customers and its compliance with the 2008 MOA, in certain respects, were  
15 inadequate.”

16 693. Thereafter, on December 23, 2016, Cardinal Health agreed to pay a  
17 \$44 million fine to the DEA to resolve the civil penalty portion of the  
18 administrative action taken against its Lakeland, Florida Distribution Center.

19 694. On January 5, 2017, McKesson Corporation entered into an  
20 *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a  
21 \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to  
22 identify and report suspicious orders at its facilities in Aurora CO, Aurora IL,  
23 Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI,  
24 Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West  
25 Sacramento CA.



695. In its Administrative Memorandum Agreement, McKesson acknowledged its wrongdoing and failure to comply with the obligations imposed by the CSA:

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

696. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis.

697. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA. The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. Documents published by the L.A. Times reveal that a Purdue sales manager spoke with company officials, asking:

698. Purdue was clearly aware of diversion. As a registrant, Purdue has the same obligation to report suspicious orders as a wholesale distributor. Although Purdue claimed that it was considering making a report to the DEA, it

1 shirked its responsibility, claimed that it was the wholesaler's responsibility and  
2 then reserved the right to make the report:

3 699. Despite its knowledge of obvious diversion, "Purdue did not shut off  
4 the supply of highly addictive OxyContin and did not tell authorities what it knew  
5 about [a pill mill] until several years later when the clinic was out of business and  
6 its leaders indicted. By that time, 1.1 million pills had spilled into the hands of  
7 Armenian mobsters, the Crips gang and other criminals."

8 700. Finally, Mallinckrodt was recently the subject of a DEA and Senate  
9 investigation for its opioid practices. Specifically, in 2011, the DEA targeted  
10 Mallinckrodt arguing that it ignored its responsibility to report suspicious orders  
11 as 500 million of its pills ended up in Florida between 2008 and 2012. After six  
12 years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35  
13 million fine. Federal prosecutors summarized the case by saying that  
14 Mallinckrodt's response was that everyone knew what was going on in Florida but  
15 they had no duty to report it.

16 701. These actions against the Distributor Defendants confirm that the  
17 Distributor Defendants knew they had a duty to maintain effective controls against  
18 diversion, design and operate a system to disclose suspicious orders, and to report  
19 suspicious orders to the DEA. These actions also demonstrate, on information and  
20 belief, that the Manufacturer Defendants were aware of the enforcement against  
21 their Distributors and the diversion of the prescription opioids and a  
22 corresponding duty to report suspicious orders.

23 702. The pattern of racketeering activity alleged herein is continuing as of  
24 the date of this Complaint and, upon information and belief, will continue into the  
25 future unless enjoined by this Court.

26 703. Many of the precise dates of the RICO Diversion Defendants'  
27 criminal actions at issue herein were hidden and cannot be alleged without access  
28 to their books and records. Indeed, an essential part of the successful operation of

1 the Opioid Diversion Enterprise depended upon the secrecy of the participants in  
2 that enterprise.

3 704. Each instance of racketeering activity alleged herein was related, had  
4 similar purposes, involved the same or similar participants and methods of  
5 commission, and had similar results affecting similar victims, Plaintiffs'  
6 Community and the County. Defendants calculated and intentionally crafted the  
7 diversion scheme to increase and maintain profits from unlawful sales of opioids,  
8 without regard to the effect such behavior would have on this jurisdiction, its  
9 citizens or the County. The Defendants were aware that the County and the  
10 citizens of this jurisdiction rely on the Defendants to maintain a closed system of  
11 manufacturing and distribution to protect against the non-medical diversion and  
12 use of their dangerously addictive opioid drugs.

13 705. By intentionally refusing to report and halt suspicious orders of their  
14 prescription opioids, Defendants engaged in a fraudulent scheme and unlawful  
15 course of conduct constituting a pattern of racketeering activity.

16 706. The RICO Diversion Defendants' predicate acts and pattern of  
17 racketeering activity were a substantial and foreseeable cause of the County's  
18 injury and the relationship between the RICO Diversion Defendants' conduct and  
19 the County's injury are logical and not speculative. It was foreseeable to the  
20 RICO Diversion Defendants that when they refused to identify, report and halt  
21 suspicious orders as required by the CSA and Code of Federal Regulations, it  
22 would allow the wide-spread diversion of prescriptions opioids into the illicit  
23 market and create an opioid-addiction epidemic that logically, substantially, and  
24 foreseeably harmed the County.

25 707. The RICO Diversion Defendants' predicate acts and pattern of  
26 racketeering activity were a substantial and foreseeable cause of the County's  
27 injury and the relationship between the RICO Diversion Defendants' conduct and  
28 the County's injury is logical and not speculative. It was foreseeable to the RICO

1 Diversion Defendants that when they fraudulently marketed highly-addictive and  
2 dangerous drugs, that were approved for very limited and specific uses by the  
3 FDA, as non-addictive and safe for off-label uses such as moderate pain, non-  
4 cancer pain, and long-term chronic pain, that the RICO Diversion Defendants  
5 would create an opioid-addiction epidemic that logically, substantially and  
6 foreseeably harmed the County.

7 708. The last racketeering incident occurred within five years of the  
8 commission of a prior incident of racketeering.

9 **2. The RICO Diversion Defendants Engaged in Mail and**  
10 **Wire Fraud.**

11 709. The RICO Diversion Defendants carried out, or attempted to carry  
12 out, a scheme to defraud federal and state regulators, and the American public by  
13 knowingly conducting or participating in the conduct of the Opioid Diversion  
14 Enterprise through a pattern of racketeering activity within the meaning of 18  
15 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of  
16 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

17 710. The RICO Diversion Defendants committed, conspired to commit,  
18 and/or aided and abetted in the commission of at least two predicate acts of  
19 racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the  
20 past ten years. The multiple acts of racketeering activity that the RICO Diversion  
21 Defendants committed, or aided and abetted in the commission of, were related to  
22 each other, posed a threat of continued racketeering activity, and therefore  
23 constitute a “pattern of racketeering activity.” The racketeering activity was made  
24 possible by the RICO Diversion Defendants’ regular use of the facilities, services,  
25 distribution channels, and employees of the Opioid Diversion Enterprise. The  
26 RICO Diversion Defendants participated in the scheme to defraud by using mail,  
27 telephone and the Internet to transmit mailings and wires in interstate or foreign  
28 commerce.

1           711. The RICO Diversion Defendants used, directed the use of, and/or  
2 caused to be used, thousands of interstate mail and wire communications in  
3 service of their scheme through virtually uniform misrepresentations,  
4 concealments and material omissions regarding their compliance with their  
5 mandatory reporting requirements and the actions necessary to carry out their  
6 unlawful goal of selling prescription opioids without reporting suspicious orders  
7 or the diversion of opioids into the illicit market.

8           712. In devising and executing the illegal scheme, the RICO Diversion  
9 Defendants devised and knowingly carried out a material scheme and/or artifice to  
10 defraud by means of materially false or fraudulent pretenses, representations,  
11 promises, or omissions of material facts. For the purpose of executing the illegal  
12 scheme, the RICO Diversion Defendants committed these racketeering acts,  
13 which number in the thousands, intentionally and knowingly with the specific  
14 intent to advance the illegal scheme.

15           713. The RICO Diversion Defendants' predicate acts of racketeering (18  
16 U.S.C. § 1961(1)) include, but are not limited to:

17           a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by  
18 sending or receiving, or by causing to be sent and/or received, materials  
19 via U.S. mail or commercial interstate carriers for the purpose of  
20 executing the unlawful scheme to design, manufacture, market, and sell  
21 the prescription opioids by means of false pretenses, misrepresentations,  
22 promises, and omissions.

23           b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by  
24 transmitting and/or receiving, or by causing to be transmitted and/or  
25 received, materials by wire for the purpose of executing the unlawful  
26 scheme to design, manufacture, market, and sell the prescription opioids  
27 by means of false pretenses, misrepresentations, promises, and  
28 omissions.

1           714. The RICO Diversion Defendants' use of the mail and wires includes,  
2 but is not limited to, the transmission, delivery, or shipment of the following by  
3 the Manufacturers, Distributors, or third parties that were foreseeably caused to be  
4 sent as a result of the RICO Diversion Defendants' illegal scheme, including but  
5 not limited to:

- 6           a. The prescription opioids themselves;
- 7           b. Documents and communications that supported and/or facilitated the  
8           Defendants' request for higher aggregate production quotas, individual  
9           production quotas, and procurement quotas;
- 10          c. Documents and communications that facilitated the manufacture,  
11          purchase and sale of prescription opioids;
- 12          d. Defendants' DEA registrations;
- 13          e. Documents and communications that supported and/or facilitated  
14          Defendants' DEA registrations;
- 15          f. Defendants' records and reports that were required to be submitted to the  
16          DEA pursuant to 21 U.S.C. § 827;
- 17          g. Documents and communications related to the Defendants' mandatory  
18          DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- 19          h. Documents intended to facilitate the manufacture and distribution of  
20          Defendants' prescription opioids, including bills of lading, invoices,  
21          shipping records, reports and correspondence;
- 22          i. Documents for processing and receiving payment for prescription  
23          opioids;
- 24          j. Payments from the Distributors to the Manufacturers;
- 25          k. Rebates and chargebacks from the Manufacturers to the Distributors;
- 26          l. Payments to Defendants' lobbyists through the PCF;
- 27          m. Payments to Defendants' trade organizations, like the HDA, for  
28          memberships and/or sponsorships;



n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

715. On information and belief, the RICO Diversion Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycontin	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (wholly-owned subsidiary of Endo)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt PLC, (2) Mallinckrodt LLC (wholly-owned subsidiary of Mallinckrodt PLC)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Allergan	(1) Allergan Plc, (2) Actavis LLC, (3) Actavis Pharma, Inc., (4) Actavis Plc, (5) Actavis, Inc., (6) Watson Pharmaceuticals, Inc., (7) Watson Pharma, Inc.	Kadian	Morphine Sulfate	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

716. Each of the RICO Diversion Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

717. The RICO Diversion Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Diversion Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

718. At the same time, the RICO Diversion Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

719. Upon information and belief, the RICO Diversion Defendants utilized the internet and other electronic resources to exchange communications,

1 to exchange information regarding prescription opioid sales, and to transmit  
2 payments and rebates/chargebacks.

3 720. The RICO Diversion Defendants also communicated by U.S. Mail,  
4 by interstate facsimile, and by interstate electronic mail with each other and with  
5 various other affiliates, regional offices, regulators, distributors, and other third-  
6 party entities in furtherance of the scheme.

7 721. The mail and wire transmissions described herein were made in  
8 furtherance of Defendants' scheme and common course of conduct to deceive  
9 regulators, the public and The County that Defendants were complying with their  
10 state and federal obligations to identify and report suspicious orders of  
11 prescription opioids all while Defendants were knowingly allowing millions of  
12 doses of prescription opioids to divert into the illicit drug market. The RICO  
13 Diversion Defendants' scheme and common course of conduct was to increase or  
14 maintain high production quotas for their prescription opioids from which they  
15 could profit.

16 722. Many of the precise dates of the fraudulent uses of the U.S. mail and  
17 interstate wire facilities have been deliberately hidden by Defendants and cannot  
18 be alleged without access to Defendants' books and records. However, Plaintiffs  
19 have described the types of, and in some instances, occasions on which the  
20 predicate acts of mail and/or wire fraud occurred. They include thousands of  
21 communications to perpetuate and maintain the scheme, including the things and  
22 documents described in the preceding paragraphs.

23 723. The RICO Diversion Defendants did not undertake the practices  
24 described herein in isolation, but as part of a common scheme. Various other  
25 persons, firms, and corporations, including third-party entities and individuals not  
26 named as defendants in this Complaint, may have contributed to and/or  
27 participated in the scheme with the RICO Diversion Defendants in these offenses  
28 and have performed acts in furtherance of the scheme to increase revenues,

1 increase market share, and /or minimize the losses for the RICO Diversion  
2 Defendants.

3 724. The RICO Diversion Defendants aided and abetted others in the  
4 violations of the above laws, thereby rendering them indictable as principals in the  
5 18 U.S.C. §§ 1341 and 1343 offenses.

6 725. The RICO Diversion Defendants hid from the general public and  
7 suppressed and/or ignored warnings from third parties, whistleblowers and  
8 governmental entities about the reality of the suspicious orders that the RICO  
9 Diversion Defendants were filling on a daily basis – leading to the diversion of  
10 hundreds of millions of doses of prescriptions opioids into the illicit market.

11 726. The RICO Diversion Defendants, with knowledge and intent, agreed  
12 to the overall objective of their fraudulent scheme and participated in the common  
13 course of conduct to commit acts of fraud and indecency in manufacturing and  
14 distributing prescription opioids.

15 727. Indeed, for the Defendants' fraudulent scheme to work, each of the  
16 Defendants had to agree to implement similar tactics regarding manufacturing  
17 prescription opioids and refusing to report suspicious orders.

18 728. As described herein, the RICO Diversion Defendants engaged in a  
19 pattern of related and continuous predicate acts for years. The predicate acts  
20 constituted a variety of unlawful activities, each conducted with the common  
21 purpose of obtaining significant monies and revenues from the sale of their highly  
22 addictive and dangerous drugs. The predicate acts also had the same or similar  
23 results, participants, victims, and methods of commission. The predicate acts were  
24 related and not isolated events.

25 729. The predicate acts all had the purpose of creating the opioid epidemic  
26 that substantially injured the County's business and property, while  
27 simultaneously generating billion-dollar revenue and profits for the RICO  
28 Diversion Defendants. The predicate acts were committed or caused to be

1 committed by the RICO Diversion Defendants through their participation in the  
2 Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

3 730. The pattern of racketeering activity alleged herein and the Opioid  
4 Diversion Enterprise are separate and distinct from each other. Likewise,  
5 Defendants are distinct from the enterprise.

6 731. The pattern of racketeering activity alleged herein is continuing as of  
7 the date of this Complaint and, upon information and belief, will continue into the  
8 future unless enjoined by this Court.

9 732. Many of the precise dates of the RICO Diversion Defendants'  
10 criminal actions at issue here have been hidden by Defendants and cannot be  
11 alleged without access to Defendants' books and records. Indeed, an essential part  
12 of the successful operation of the Opioid Diversion Enterprise alleged herein  
13 depended upon secrecy.

14 733. Each instance of racketeering activity alleged herein was related, had  
15 similar purposes, involved the same or similar participants and methods of  
16 commission, and had similar results affecting similar victims, including Plaintiffs'  
17 Community and the County. Defendants calculated and intentionally crafted the  
18 Opioid Diversion Enterprise and their scheme to increase and maintain their  
19 increased profits, without regard to the effect such behavior would have on  
20 Plaintiffs' Community, its citizens or the County. In designing and implementing  
21 the scheme, at all times Defendants were cognizant of the fact that those in the  
22 manufacturing and distribution chain rely on the integrity of the pharmaceutical  
23 companies and ostensibly neutral third parties to provide objective and reliable  
24 information regarding Defendants' products and their manufacture and  
25 distribution of those products. The Defendants were also aware that The County  
26 and the citizens of this jurisdiction rely on the Defendants to maintain a closed  
27 system and to protect against the non-medical diversion and use of their  
28 dangerously addictive opioid drugs.

734. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

735. It was foreseeable to Defendants that The County would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

736. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

#### **D. DAMAGES.**

##### **1. Impact of the Opioid Diversion Enterprise.**

737. California has been especially ravaged by the national opioid crisis.

738. More people die each year from drug overdoses in California than in any other state.<sup>485</sup> The State's death rate has continued to climb, increasing by 30 percent from 1999 to 2015, according to the Center for Disease Control (CDC).<sup>486</sup>

739. In 2016, 1,925 Californians died due to prescription opioids.<sup>487</sup> This number is on par with other recent years: in 2015, 1,966 deaths in California were due just to prescription opioids (not including heroin); in 2014 that number was even higher at 2,024 prescription opioid deaths; and in 2013, 1,934 Californians died from a prescription opioid overdose.<sup>488</sup>

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<sup>485</sup> Davis, *supra*.

<sup>486</sup> Karlamangla, *supra*.

<sup>487</sup> Davis, *supra*.

<sup>488</sup> California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last visited March 2, 2018).



740. Of the 1,925 opioid-related deaths in California in 2016, fentanyl was a factor in at least 234 of them.<sup>489</sup> This is an increase of 47 percent for 2016.<sup>490</sup> Heroin-related deaths have risen by 67 percent in California since 2006.<sup>491</sup>

741. The high number of deaths is due in part to the extraordinary number of opioids prescribed in the State. Over 23.6 million prescriptions for opioids were written in California in just 2016.<sup>492</sup>

742. The California Department of Public Health tracks the number of reported hospitalizations and emergency department visits due to prescription opioids.<sup>493</sup> In 2015, the last year for which information is currently available, California had 3,935 emergency department visits and 4,095 hospitalizations related to prescription opioid overdoses (excluding heroin).<sup>494</sup> The numbers were even higher in 2014, when 4,106 people visited the emergency department and 4,482 people were hospitalized due to prescription opioid abuse.<sup>495</sup> In 2013, there were 3,964 emergency department visits and 4,344 hospitalizations for prescription opioid overdoses.<sup>496</sup> When emergency visits and hospitalizations include heroin, the numbers are even higher.<sup>497</sup>

<sup>489</sup> Davis, *supra*.

<sup>490</sup> Karlamangla, *supra*.

<sup>491</sup> California Department of Public Health, *State of California Strategies to Address Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in California* at 3 (June 2016), available at <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Document%20Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited March 2, 2018).

<sup>492</sup> California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, *supra*.

493 *Id.*

494 *Id.*495 *Id.*

496 *Id.*

497 *Id.*

1           743. NAS has increased dramatically in California, with the rate of infants  
2 born with NAS more than tripling from 2008 to 2013.<sup>498</sup> While the number of  
3 affected newborns rose from 1,862 in 2008 to 3,007 in 2014, that number jumped  
4 by another 21 percent in 2015.<sup>499</sup> This is despite a steady decline in the overall  
5 number of birth in California during that same time.<sup>500</sup>

6           744. Reports from California's Office of Statewide Health Planning,  
7 which collects data from licensed health care facilities, have shown a 95 percent  
8 increase between 2008 and 2015 of newborns affected by drugs transmitted via  
9 placenta or breast milk.<sup>501</sup>

10           745. The opioid epidemic has also had an impact on crime in California.  
11 Pharmacy robberies have gone up by 163 percent in California over the last two  
12 years, according to the DEA. The DEA recorded 90 incidents in 2015, 154 in  
13 2016 and, through mid-November of 2017, that number had climbed to 237.<sup>502</sup>  
14 Most perpetrators were after prescription opioids.<sup>503</sup> In addition, fentanyl seizures  
15 at California ports increased 266 percent in fiscal year 2017.<sup>504</sup>

16           746. The opioid epidemic is particularly devastating in Plaintiffs'  
17 Community.

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19  
20  
21 <sup>498</sup> California Child Welfare Co-Investment Partnership, *supra* at 5.

22 <sup>499</sup> Clark, *supra*.

23 <sup>500</sup> *Id.*

<sup>501</sup> California Child Welfare Co-Investment Partnership, *supra*.

24 <sup>502</sup> Ed Fletcher, "What's behind the spike in drug store robberies?" *The Sacramento*  
25 *Bee*, Dec. 8, 2017 (available at  
<http://www.sacbee.com/news/local/crime/article188636384.html> (last visited  
26 March 2, 2018)).

<sup>503</sup> *Id.*

27 <sup>504</sup> United State Department of Justice, The United States Attorney's Office,  
28 Southern District of California, *U.S. Attorney Appoints Opioid Coordinators* (Feb.  
8, 2018) available at [https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-](https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators)  
[opioid-coordinators](https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators) (last visited March 2, 2018).

1           747. In 2016, the County endured 17 deaths due to opioid overdoses, for a  
2 death rate of 17.3 per 100,000 people, the fifth highest in the State.<sup>505</sup> In 2015, the  
3 County's opioid overdose death rate was in the highest quartile in the State with a  
4 rate of 15 deaths per 100,000 residents.<sup>506</sup> In 2014 the death rate was 16.96.<sup>507</sup>

5           748. This is part of a long-standing trend. From 2009 to 2013, the County  
6 had 38 deaths due to opioid pharmaceuticals, for the ninth highest death rate in the  
7 State.<sup>508</sup>

8           749. From 2012 to 2014, the County suffered 52 deaths due to drug  
9 overdoses for a drug overdose mortality rate of 20 deaths per 100,000 residents.<sup>509</sup>

10          750. Prescription opioids have also been responsible for a high rate of  
11 emergency department visits in the County. In 2016, Mendocino County had a  
12 rate of 30.6 emergency department visits per 100,000 residents due to opioid  
13 overdoses (excluding heroin).<sup>510</sup>

16 <sup>505</sup> California Department of Public Health, *California Opioid Overdose*  
17 *Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last  
visited April 20, 2018) (Mendocino County specific page).

18 <sup>506</sup> Public Health Institute, *Tackling An Epidemic: An Assessment of the California*  
19 *Opioid Safety Coalitions Network*, at p. 11, available at  
20 <https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27ttdpzxmbclj7cxq99alz.pdf> (last visited April 20, 2018); *see also* Safe Rx  
Mendocino, Opioid Safety Coalition, available at  
<https://www.saferxmendocino.com/> (last visited April 21, 2018).

21 <sup>507</sup> Safe Rx Mendocino, Opioid Safety Coalition, available at  
22 <https://www.saferxmendocino.com/> (last visited April 21, 2018).

23 <sup>508</sup> California Department of Public Health, *State of California Strategies to*  
24 *Address Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in*  
25 *California* at 4 (June 2016), available at  
<https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Document%20Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited April 20, 2018).

26 <sup>509</sup> County Health Rankings & Roadmaps, Drug overdose deaths, available at  
27 <http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/data>  
(last visited April 20, 2018).

28 <sup>510</sup> California Department of Public Health, *California Opioid Overdose*  
*Surveillance Dashboard*, available at [https://pdop.shinyapps.io/ODdash\\_v1/](https://pdop.shinyapps.io/ODdash_v1/) (last  
visited April 20, 2018) (Mendocino County specific page).

751. The CDC has tracked prescription rates per county in the United States, identifying the geographic “hotspots” for rates of opioid prescriptions.<sup>511</sup> The CDC has calculated the geographic distribution at county levels of opioid prescriptions dispensed per 100 persons,<sup>512</sup> revealing that Mendocino County has been a consistent hotspot over at least the past decade.

752. The CDC’s statistics prove that the opioid prescription rates in Mendocino County have exceeded any legitimate medical, scientific, or industrial purpose. The overall opioid prescribing rate in 2016 was 66.5 prescriptions per 100 people and 44.8 in California.<sup>513</sup> However, in Mendocino County, California, the 2016 prescription rate was 105.1 per 100 people – more than one prescription for every man, woman and child in Mendocino County and one of the highest prescribing rates in the State.<sup>514</sup> This is down from the 2015 prescribing rate for Mendocino County which was 118.2 per 100 people.<sup>515</sup>

753. Unfortunately, the 2015 and 2016 high rates of opioid prescriptions were not an aberration for Mendocino County. Consistently, the opioid prescribing rates in Mendocino County have been among the highest in the state, significantly greater than the national and state averages, and well more than one prescription per person living in the County. Compared to a national average of

<sup>511</sup> U.S. Prescribing Rate Maps, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30, 2017).

<sup>512</sup> *Id.*

<sup>513</sup> *Id.* See also U.S. State Prescribing Rates, 2016, available at <https://www.cdc.gov/drugoverdose/maps/rxstate2016.html> (last visited April 18, 2018).

<sup>514</sup> U.S. County Prescribing Rates, 2016, (reporting for “Mendocino, CA” here and below) CDC available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited April 18, 2018).

<sup>515</sup> U.S. County Prescribing Rates, 2015, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html> (last visited April 18, 2018).

1 75.6 opioid prescriptions per 100 people in 2014<sup>516</sup> and 52.7 in California,<sup>517</sup> the  
 2 Mendocino County opioid prescription rate was 127.2 per 100 people.<sup>518</sup> In 2013,  
 3 the national average was 78.1 opioid prescriptions per 100 people,<sup>519</sup> but the  
 4 opioid prescription rate in Mendocino County was 129.4 per 100 people.<sup>520</sup>  
 5 Compared to a national average of 81.3 opioid prescriptions per 100 people in  
 6 2012,<sup>521</sup> the opioid prescription rate in Mendocino County was 137.2 per 100  
 7 people that year – an all-time high for Mendocino County.<sup>522</sup> In 2011, the national  
 8 average was 80.9 opioid prescriptions per 100 people,<sup>523</sup> but the opioid  
 9 prescription rate in Mendocino County was 137 per 100 people.<sup>524</sup> Compared to a  
 10 national average of 81.2 opioid prescriptions per 100 people in 2010,<sup>525</sup> the

11  
 12 <sup>516</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 13 2017).

14 <sup>517</sup> U.S. State Prescribing Rates, 2014, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxstate2014.html> (last visited Dec. 11,  
 15 2017).

16 <sup>518</sup> U.S. County Prescribing Rates, 2014, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html> (last visited April 18,  
 17 2018).

18 <sup>519</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 19 2017).

20 <sup>520</sup> U.S. County Prescribing Rates, 2013, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2013.html> (last visited April 18,  
 21 2018).

22 <sup>521</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 23 2017).

24 <sup>522</sup> U.S. County Prescribing Rates, 2012, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html> (last visited April 18,  
 25 2018).

26 <sup>523</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 27 2017).

28 <sup>524</sup> U.S. County Prescribing Rates, 2011, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html> (last visited April 18,  
 2018).

<sup>525</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 2017).

1 Mendocino County opioid prescription rate was 135.1 per 100 people.<sup>526</sup> In 2009,  
 2 the national average was 79.5 opioid prescriptions per 100 people,<sup>527</sup> but the rate  
 3 in Mendocino County was 129.4.5 per 100.<sup>528</sup> Compared to a national average of  
 4 78.2 opioid prescriptions per 100 people in 2008<sup>529</sup> and 55.1 in California,<sup>530</sup> the  
 5 Mendocino County rate was 128.6 per 100 people.<sup>531</sup> In 2007, the national  
 6 average was 75.9 opioid prescriptions per 100 people,<sup>532</sup> but the Mendocino  
 7 County rate was 121.6 per 100 people.<sup>533</sup> Compared to a national average of 72.4  
 8 opioid prescriptions per 100 people prescribed opioids in 2006,<sup>534</sup> the Mendocino  
 9 County rate was 114.1 per 100 people.<sup>535</sup>

10  
 11  
 12 <sup>526</sup> U.S. County Prescribing Rates, 2010, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html> (last visited April 18,  
 13 2018).

14 <sup>527</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 15 2017).

16 <sup>528</sup> U.S. County Prescribing Rates, 2009, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2009.html> (last visited April 18,  
 17 2018).

18 <sup>529</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 19 2017).

20 <sup>530</sup> U.S. State Prescribing Rates, 2018, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxstate2008.html> (last visited Dec. 11,  
 21 2017).

22 <sup>531</sup> U.S. County Prescribing Rates, 2008, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2008.html> (last visited April 18,  
 23 2018).

24 <sup>532</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,,  
 25 2017).

26 <sup>533</sup> U.S. County Prescribing Rates, 2007, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2007.html> (last visited April 18,  
 27 2018).

28 <sup>534</sup> U.S. Prescribing Rate Maps, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,  
 2017).

<sup>535</sup> U.S. County Prescribing Rates, 2006, CDC, available at  
<https://www.cdc.gov/drugoverdose/maps/rxcounty2006.html> (last visited April 18,  
 2018).



1                                   **2.     The Relief Sought.**

2           754. The RICO Diversion Defendants' violations of law and their pattern  
3 of racketeering activity directly and proximately caused the County injury in its  
4 business and property. The RICO Diversion Defendants' pattern of racketeering  
5 activity, including their refusal to identify, report and halt suspicious orders of  
6 controlled substances, logically, substantially and foreseeably cause an opioid  
7 epidemic. The County was injured by the RICO Diversion Defendants' pattern of  
8 racketeering activity and the opioid epidemic that they created.

9           755. As the County alleges, the RICO Diversion Defendants knew that the  
10 opioids they manufactured and supplied were unsuited to treatment of long-term,  
11 chronic, non-acute, and non-cancer pain, or for any other use not approved by the  
12 FDA, and knew that opioids were highly addictive and subject to abuse.<sup>536</sup>  
13 Nevertheless, the RICO Diversion Defendants engaged in a scheme of deception,  
14 that utilized the mail and wires as part of their fraud, in order to increase sales of  
15 their opioid products by refusing to identify, report suspicious orders of  
16 prescription opioids that they knew were highly addictive, subject to abuse, and  
17 were actually being diverted into the illegal market.<sup>537</sup>

18           756. Here, as the County alleges, the link of causation generally breaks  
19 down into three very short steps: (1) the RICO Diversion Defendants' affirmative  
20 action to continue supplying prescription opioids through legal channels with  
21 knowledge that they were being diverted into the illicit market; (2) an opioid  
22 epidemic in the form of criminal drug trafficking, misuse and abuse; and (3)  
23 injuries to the County.<sup>538</sup> Although not as direct as a car accident or a slip-and-fall  
24

25  
26 <sup>536</sup> Traveler's Property Casualty Company of America v. Actavis, Inc., 22 Cal.  
Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

27 <sup>537</sup> *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, \*6 (W.D. Wash.  
Sept. 25, 2017).

28 <sup>538</sup> *Id.*

1 case, this causal chain is still a “direct sequence” and a logical, substantial and  
 2 foreseeable cause of the County’s injury.<sup>539</sup>

3 757. Specifically, the RICO Diversion Defendants’ predicate acts and  
 4 pattern of racketeering activity caused the opioid epidemic which has injured the  
 5 County in the form of substantial losses of money and property that logically,  
 6 directly and foreseeably arise from the opioid-addiction epidemic. The County’s  
 7 injuries, as alleged throughout this complaint, and expressly incorporated herein  
 8 by reference, include:

- 9 a. Losses caused by purchasing and/or paying reimbursements for the  
 10 RICO Defendants’ prescription opioids, that The County would not have  
 11 paid for or purchased but for the RICO Diversion Defendants’ conduct;
- 12 b. Losses caused by the decrease in funding available for The County’s  
 13 public services for which funding was lost because it was diverted to  
 14 other public services designed to address the opioid epidemic;
- 15 c. Costs for providing healthcare and medical care, additional therapeutic,  
 16 and prescription drug purchases, and other treatments for patients  
 17 suffering from opioid-related addiction or disease, including overdoses  
 18 and deaths;
- 19 d. Costs of training emergency and/or first responders in the proper  
 20 treatment of drug overdoses;
- 21 e. Costs associated with providing police officers, firefighters, and  
 22 emergency and/or first responders with Naloxone – an opioid antagonist  
 23 used to block the deadly effects of opioids in the context of overdose;
- 24 f. Costs associated with emergency responses by police officers,  
 25 firefighters, and emergency and/or first responders to opioid overdoses;

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26  
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28 <sup>539</sup> *Id.*

- 1 g. Costs for providing mental-health services, treatment, counseling,  
2 rehabilitation services, and social services to victims of the opioid  
3 epidemic and their families;
- 4 h. Costs for providing treatment of infants born with opioid-related medical  
5 conditions, or born addicted to opioids due to drug use by mother during  
6 pregnancy;
- 7 i. Costs associated with law enforcement and public safety relating to the  
8 opioid epidemic, including but not limited to attempts to stop the flow of  
9 opioids into local communities, to arrest and prosecute street-level  
10 dealers, to prevent the current opioid epidemic from spreading and  
11 worsening, and to deal with the increased levels of crimes that have  
12 directly resulted from the increased homeless and drug-addicted  
13 population;
- 14 j. Costs associated with increased burden on the County's judicial system,  
15 including increased security, increased staff, and the increased cost of  
16 adjudicating criminal matters due to the increase in crime directly  
17 resulting from opioid addiction;
- 18 k. Costs associated with providing care for children whose parents suffer  
19 from opioid-related disability or incapacitation;
- 20 l. Loss of tax revenue due to the decreased efficiency and size of the  
21 working population in Plaintiffs' Community;
- 22 m. Losses caused by diminished property values in neighborhoods where  
23 the opioid epidemic has taken root; and
- 24 n. Losses caused by diminished property values in the form of decreased  
25 business investment and tax revenue.

26 758. The County's injuries were proximately caused by Defendants'  
27 racketeering activities because they were the logical, substantial and foreseeable  
28

1 cause of The County's injuries. But for the opioid-addiction epidemic created by  
2 Defendants' conduct, The County would not have lost money or property.

3 759. The County's injuries were directly caused by the RICO Diversion  
4 Defendants' pattern of racketeering activities.

5 760. The County is most directly harmed and there is no other Plaintiff  
6 better suited to seek a remedy for the economic harms at issue here.

7 761. Plaintiff seeks all legal and equitable relief as allowed by law,  
8 including *inter alia* actual damages, treble damages, equitable relief, forfeiture as  
9 deemed proper by the Court, attorney's fees and all costs and expenses of suit and  
10 pre- and post-judgment interest

## 11 **COUNT V**

### 12 **FALSE ADVERTISING**

#### 13 **Violations of California Business and Professions Code section 17500, et seq.** 14 **(Against All Defendants)**

15 762. Plaintiff, The People, incorporate by reference all other paragraphs of  
16 this Complaint as if fully set forth here, and further alleges as follows.

17 763. This Count is brought by the People of the State. This Count is  
18 brought pursuant to Sections 17535 and 17536 of the California Business and  
19 Professions Code for injunctive relief, restitution and civil penalties.

20 764. Section 17500 of the California Business and Professions Code  
21 makes it "unlawful for any person, . . . corporation . . . with intent directly or  
22 indirectly to dispose of real or personal property . . . or to induce the public to  
23 enter into any obligation relating thereto, to make or disseminate or cause to be  
24 made or disseminated before the public in this state, . . . in any . . . manner or  
25 means whatever . . . any statement, concerning that real or personal property . . .  
26 which is untrue or misleading, and which is known, or which by the exercise of  
27 reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof.  
28 Code § 17500.

1           765. As described above in allegations expressly incorporated herein, at  
2 all times relevant to this Complaint, Defendants directly and indirectly violated  
3 Section 17500 by making and disseminating untrue, false and misleading  
4 statements about, *inter alia*, the use of opioids for chronic pain, about the risks of  
5 addiction related to opioids, about the signs of addiction and how to reliably  
6 identify and safely prescribe opioids to patients predisposed to addiction, and  
7 about their so-called abuse-deterrent opioid formulations. Defendants also  
8 repeatedly failed to disclose material facts about the risks of opioids.

9           766. The Manufacturer Defendants also made untrue, false, and  
10 misleading statements that included, but were not limited to:

11           767. Claiming or implying that opioids would improve patients' function  
12 and quality of life;

13           768. Claiming that opioids should be used to treat chronic pain and that  
14 there was a significant upside to long-term opioid use;

15           769. Mischaracterizing the risk of opioid addiction and abuse, including  
16 by stating or implying the opioids were rarely addictive, that "steady state" and  
17 abuse-resistant properties meant the drugs were less likely to be addictive or  
18 abused, and that specific opioid drugs were less addictive or less likely to be  
19 abused than other opioids;

20           770. Claiming or implying that addiction can be avoided or successfully  
21 managed through the use of screening and other tools and exaggerating the  
22 effectiveness of screening tools to prevent addiction;

23           771. Promoting the misleading concept of pseudoaddiction, thus  
24 concealing the true risk of addiction, and advocating that the signs of addiction  
25 should be treated with more opioids;

26           772. Mischaracterizing the difficulty of discontinuing opioid therapy,  
27 including by mischaracterizing the prevalence and severity of withdrawal  
28

1 symptoms, and claiming that opioid dependence and withdrawal are easily  
2 managed;

3 773. Claiming of implying that increased doses of opioids pose no  
4 significant additional risk;

5 774. Misleadingly depicting the safety profile of opioids prescribed by  
6 minimizing their risks and adverse effects while emphasizing or exaggerating the  
7 risks of competing products, including NSAIDs; and

8 775. In the case of Purdue, mischaracterizing OxyContin's onset of action  
9 and duration of efficacy to imply that the drug provided a full 12 hours of pain  
10 relief.

11 776. The Manufacturer Defendants made deceptive representations to the  
12 public about the use of opioids to treat chronic non-cancer pain. Each  
13 Manufacturer Defendant also omitted or concealed material facts and failed to  
14 correct prior misrepresentations and omissions to the public about the risks and  
15 benefits of opioids. Each Defendant's omissions rendered even their seemingly  
16 truthful statements about opioids deceptive.

17 777. Defendants' conduct was likely to mislead or deceive The People and  
18 Plaintiffs' Community, including Californians who purchased or covered or paid  
19 for the purchase of opioids for chronic pain.

20 778. Each Manufacturer Defendant has conducted, and has continued to  
21 conduct, a widespread marketing scheme designed to promote opioids and  
22 persuade doctors and patients that opioids can and should be used for chronic  
23 pain, resulting in opioid treatment for a far broader group of patients who are  
24 much more likely to become addicted and suffer other adverse effects from the  
25 long-term use of opioids. In connection with this scheme, each Manufacturer  
26 Defendant spent, and continues to spend, millions of dollars on promotional  
27 activities and materials that falsely deny or trivialize the risks of opioids while  
28 overstating the benefits of using them for chronic pain. This conduct tends to



1 mislead or deceive, and has misled and deceived, The People and Plaintiffs'  
2 Community.

3 779. The Manufacturer Defendants have disseminated these common  
4 messages to reverse the popular and medical understanding of opioids and risks of  
5 opioid use. They disseminated these messages directly, through their sales  
6 representatives, in speaker groups led by physicians the Manufacturer Defendants  
7 recruited for their support of their marketing messages, and through unbranded  
8 marketing and industry-funded front groups.

9 780. Pursuant to Section 17535 of the California Business and Professions  
10 Code, The People request an order from this Court enjoining Defendants from any  
11 further violations of the California False Advertising law, California Business and  
12 Professions Code §§ 17500 *et seq.*

13 781. Pursuant to Section 17535 of the California Business and Professions  
14 Code, the People request restitution of any money acquired by Defendants'  
15 violations of the California False Advertising law, California Business and  
16 Professions Code §§ 17500 *et seq.*

17 782. Pursuant to Section 17536 of the California Business and Professions  
18 Code, The People request an order assessing a civil penalty of two thousand five  
19 hundred dollars (\$2,500) against Defendants for each violation of the California  
20 False Advertising law, California Business and Professions Code §§ 17500 *et seq.*

## 21 **COUNT VI**

### 22 **NEGLIGENT MISREPRESENTATION**

#### 23 **(Against All Defendants)**

24 783. Plaintiff, The County, incorporates by reference all other paragraphs  
25 of this Complaint as if fully set forth here, and further alleges as follows.

26 784. The County seeks economic damages which were the foreseeable  
27 result of the Defendants' intentional and/or unlawful actions and omissions.  
28

1           785. California classifies negligent misrepresentation as a species of fraud  
 2 or deceit for which economic losses are recoverable. *Kalitta Air, L.L.C. v. Cent.*  
 3 *Texas Airborne Sys., Inc.*, 315 F. App'x 603, 607 (9th Cir. 2008) (citing *Bily v.*  
 4 *Arthur Young & Co.*, 3 Cal. 4th 370, 11 Cal. Rptr. 2d 51, 834 P.2d 745, 768  
 5 (1992)).

6           786. The elements of negligent misrepresentation in California are that the  
 7 defendant: (1) made a misrepresentation of a past or existing material fact, (2)  
 8 without reasonable grounds for believing it to be true, (3) with the intent to induce  
 9 another's reliance on the misrepresentation, (4) justifiable reliance on the  
 10 misrepresentation, and (5) resulting damage. *Wells Fargo Bank, N.A. v. FSI, Fin.*  
 11 *Sols., Inc.*, 196 Cal. App. 4th 1559, 1573, 127 Cal. Rptr. 3d 589, 600 (2011); *Fox*  
 12 *v. Pollack*, 181 Cal. App. 3d 954, 962, 226 Cal. Rptr. 532, 536–37 (Ct. App.  
 13 1986). Negligent misrepresentation “encompasses ‘[t]he assertion, as a fact, of  
 14 that which is not true, by one who has no reasonable ground for believing it to be  
 15 true.’” *Small v. Fritz Companies, Inc.*, 30 Cal. 4th 167, 173–74, 65 P.3d 1255,  
 16 1258 (2003) (citing Cal. Civ. Code § 1710(2)).

17           787. As described elsewhere in this Complaint in allegations expressly  
 18 incorporated herein, Distributor Defendants misrepresented their compliance with  
 19 their duties under the law and concealed their noncompliance and shipments of  
 20 suspicious orders of opioids to Plaintiffs’ Community and destinations from  
 21 which they knew opioids were likely to be diverted into Plaintiffs’ Community, in  
 22 addition to other misrepresentations alleged and incorporated herein.

23           788. As described elsewhere in the Complaint in allegations expressly  
 24 incorporated herein, Manufacturer Defendants breached their duties to exercise  
 25 due care in the business of pharmaceutical manufacturers of dangerous opioids,  
 26 which are Schedule II Controlled Substances, by misrepresenting the nature of the  
 27 drugs and aggressively promoting them for chronic pain for which they knew the  
 28 drug were not safe or suitable.

1           789. The Manufacturer Defendants misrepresented and concealed the  
2 addictive nature of prescription opioids and their lack of suitability for chronic  
3 pain, in addition to other misrepresentations alleged and incorporated herein.

4           790. All Defendants breached their duties to prevent diversion and report  
5 and halt suspicious orders, and they misrepresented their compliance with their  
6 legal duties. Defendants knew or should have known that the representations they  
7 were making were untrue because they did not have reasonable grounds for  
8 believing their statements to be true.

9           791. Defendants made these false representations and concealed facts with  
10 knowledge of the falsity of their representations, or without reasonable grounds  
11 for believing them to be true, and did so with the intent of inducing reliance by  
12 The County, Plaintiffs' Community, the public, and persons on whom The County  
13 relied.

14           792. These false representations and concealments were reasonably  
15 calculated to deceive The County, Plaintiffs' Community, and the physicians who  
16 prescribed opioids for persons in Plaintiffs' Community, were made with the  
17 intent of inducing reliance, and did in fact deceive these persons, The County, and  
18 Plaintiffs' Community.

19           793. The County, Plaintiffs' Community, and the physicians who  
20 prescribed opioids reasonably relied on these false representations and  
21 concealments of material fact

22           794. The County justifiably relied on Defendants' representations and/or  
23 concealments, both directly and indirectly. This reliance proximately caused The  
24 County's injuries.

25           795. The causal connection between the Defendants' breaches of their  
26 duties and misrepresentations and the ensuing harm was entirely foreseeable.  
27  
28

1           796. As described above in allegations expressly incorporated herein,  
2 Defendants' breaches of duty and misrepresentations caused, bear a causal  
3 connection with and/or proximately resulted in the damages sought herein.

4           797. The Defendants' breaches of their duties and misrepresentations were  
5 the cause-in-fact of The County's injuries.

6           798. The risk of harm to The County and Plaintiffs' Community and the  
7 harm caused should have been reasonably foreseen by Defendants. The  
8 Defendants' conduct was substantial factor in causing The County's injuries.

9           799. The Defendants were selling dangerous drugs statutorily categorized  
10 as posing a high potential for abuse and severe dependence. The Defendants  
11 knowingly traded in drugs that presented a high degree of danger if prescribed  
12 incorrectly or diverted to other than medical, scientific, or industrial channels.  
13 However, the Defendants misrepresented what their duties were and their  
14 compliance with their legal duties.

15           800. The Defendants failed to disclose the material facts that *inter alia*  
16 they were not in compliance with laws and regulations requiring that they  
17 maintain a system to prevent diversion, protect against addiction and severe harm,  
18 and specifically monitor, investigate, report, and refuse suspicious orders. But for  
19 these material factual omissions, the Defendants would not have been able to sell  
20 opioids.

21           801. As alleged herein, each Manufacturer Defendant wrongfully  
22 represented that the opioid prescription medications they manufactured, marketed  
23 and sold had characteristics, uses or benefits that they do not have. The  
24 Manufacturer Defendants also wrongfully misrepresented that the opioids were  
25 safe and effective when the Manufacturer Defendants knew, or should have  
26 known, such representations were untrue, false and misleading.

802. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value and in fact caused addiction and overdose deaths.

803. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

804. The Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligent misrepresentation under State law.

805. The County seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the Defendants' actions and omissions.

806. The County seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

## COUNT VII

## FRAUD AND FRAUDULENT MISREPRESENTATION

**(Against All Defendants)**

807. Plaintiff, The County, incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

808. In California, the tort of fraud or intentional misrepresentation has five elements: “The elements of fraud, which gives rise to the tort action for deceit, are (a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or ‘scienter’); (c) intent to defraud, i.e.,

1 to induce reliance; (d) justifiable reliance; and (e) resulting damage.” *Small v.*  
 2 *Fritz Companies, Inc.*, 30 Cal. 4th 167, 173–74, 65 P.3d 1255, 1258 (2003) (citing  
 3 *Lazar v. Superior Court*, 12 Cal. 4th 631, 638, 49 Cal. Rptr. 2d 377, 909 P.2d 981  
 4 (1996)).

5 809. Section 1709 of the California Civil Code provides: “Fraudulent  
 6 deceit. One who willfully deceives another with intent to induce him to alter his  
 7 position to his injury or risk, is liable for any damage which he thereby suffers.”  
 8 Cal. Civ. Code. § 1709.

9 810. Section 1710 of the California Civil Code provides: “Deceit, what. A  
 10 deceit, within the meaning of the last section, is either: 1. The suggestion, as a  
 11 fact, of that which is not true, by one who does not believe it to be true; . . . 3.

12 The suppression of a fact, by one who is bound to disclose it, or who gives  
 13 information of other facts which are likely to mislead for want of communication  
 14 of that fact.” Cal. Civ. Code. §§ 1710(1) & (3). “In California, the elements of the  
 15 misrepresentation torts (which are also denominated forms of “deceit”) are  
 16 prescribed by statute . . . and our common law tradition.” *Bily v. Arthur Young &*  
 17 *Co.*, 3 Cal. 4th 370, 414, 834 P.2d 745 (1992) (citing Cal. Civ. Code § 1710).

18 811. Defendants violated their general duty not to actively deceive, have  
 19 made knowingly false statements and have omitted and/or concealed information  
 20 which made statements Defendants did make knowingly false. Defendants acted  
 21 intentionally and/or unlawfully.

22 812. As alleged herein, Defendants made false statements regarding their  
 23 compliance with state and federal law regarding their duties to prevent diversion,  
 24 their duties to monitor, report and halt suspicious orders, and/or concealed their  
 25 noncompliance with these requirements.

26 813. As alleged herein, the Manufacturer Defendants engaged in false  
 27 representations and concealments of material fact regarding the use of opioids to  
 28 treat chronic, non-cancer pain.



1           814. As alleged herein, the Defendants knowingly and/or intentionally  
2 made representations that were false. Defendants had a duty to disclose material  
3 facts and concealed them. These false representations and concealed facts were  
4 material to the conduct and actions at issue. Defendants made these false  
5 representations and concealed facts with knowledge of the falsity of their  
6 representations, and did so with the intent of misleading The County, Plaintiffs'  
7 Community, the public, and persons on whom The County relied.

8           815. These false representations and concealments were reasonably  
9 calculated to deceive The County, Plaintiffs' Community, and the physicians who  
10 prescribed opioids for persons in Plaintiffs' Community, were made with the  
11 intent to deceive and induce reliance, and did in fact deceive these persons, The  
12 County, and Plaintiffs' Community.

13           816. The County, Plaintiffs' Community, and the physicians who  
14 prescribed opioids reasonably relied on these false representations and  
15 concealments of material fact.

16           817. The County justifiably relied on Defendants' representations and/or  
17 concealments, both directly and indirectly. The County's injuries were  
18 proximately caused by this reliance.

19           818. The injuries alleged by The County herein were sustained as a direct  
20 and proximate cause of the Defendants' fraudulent conduct.

21           819. The County seeks economic losses (direct, incidental, or  
22 consequential pecuniary losses) resulting from Defendants' fraudulent activity,  
23 including fraudulent misrepresentations and fraudulent concealment.

24           820. The County seeks all legal and equitable relief as allowed by law,  
25 except as expressly disavowed herein, including *inter alia* injunctive relief,  
26 restitution, disgorgement of profits, compensatory damages and punitive damages,  
27 and all damages allowed by law to be paid by the Defendants, attorney fees and  
28 costs, and pre- and post-judgment interest.

**COUNT VIII**  
**UNJUST ENRICHMENT**  
**(Against All Defendants)**

821. Plaintiff, The County, incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

822. Defendants have unjustly retained a benefit to The County's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience. *Peterson v. Cellco Partnership*, 164 Cal. App. 4th 1583, 1593, 80 Cal. Rptr. 3d 316, 323 (2008); *Lectrodryer v. SeoulBank*, 77 Cal. App. 4th 723, 726, 91 Cal. Rptr. 2d 881 (2000).

823. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiffs' Community, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' Community.

824. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

825. The County has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

826. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

827. These expenditures have helped sustain Defendants' businesses.

828. The County has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

829. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

1           830. The County has paid for the cost of Defendants' externalities and  
2 Defendants have benefited from those payments because they allowed them to  
3 continue providing customers with a high volume of opioid products. Because of  
4 their deceptive marketing of prescription opioids, Manufacturer Defendants  
5 obtained enrichment they would not otherwise have obtained. Because of their  
6 conscious failure to exercise due diligence in preventing diversion, Defendants  
7 obtained enrichment they would not otherwise have obtained. The enrichment  
8 was without justification and the County lacks a remedy provided by law.

9           831. Defendants have unjustly retained benefits to the detriment of the  
10 County, and Defendants' retention of such benefits violates the fundamental  
11 principles of justice, equity, and good conscience.

12           832. Defendants' misconduct alleged in this case is ongoing and  
13 persistent.

14           833. Defendants' misconduct alleged in this case does not concern a  
15 discrete event or discrete emergency of the sort a political subdivision would  
16 reasonably expect to occur, and is not part of the normal and expected costs of a  
17 local government's existence. The County alleges wrongful acts which are neither  
18 discrete nor of the sort a local government can reasonably expect.

19           834. The County has incurred expenditures for special programs over and  
20 above its ordinary public services.

21           835. In addition, the County has made payments for opioid prescriptions,  
22 and Defendants benefitted from those payments. Because of their deceptive  
23 promotion of opioids, Defendants obtained enrichment they would not otherwise  
24 have obtained. The enrichment was without justification and The County lacks a  
25 remedy provided by law.

26           836. By reason of Defendants' unlawful acts, The County has been  
27 damaged and continues to be damaged, in a substantial amount to be determined  
28 at trial.

1           837. The County seeks an order compelling Defendants to disgorge all  
2 unjust enrichment to the County; and awarding such other, further, and different  
3 relief as this Honorable Court may deem just.

4                                   **PUNITIVE DAMAGES**

5           838. Plaintiffs incorporate by reference all other paragraphs of this  
6 Complaint as if fully set forth herein, and further alleges as follows.

7           839. By engaging in the above-described intentional and/or unlawful acts  
8 or practices, Defendants acted maliciously towards Plaintiffs and with an  
9 intentional disregard of the Plaintiffs' rights and the safety of Plaintiffs'  
10 Community. Defendants acted oppressively, with conscious disregard for the  
11 rights of others and/or in a reckless, wanton, willful or grossly negligent manner.  
12 Defendants acted with a prolonged intentional disregard to the adverse  
13 consequences of their actions and/or omissions. Defendants acted with a  
14 conscious disregard for the rights and safety of others in a manner that had a great  
15 probability of causing substantial harm. Defendants acted toward The County with  
16 malice and were grossly negligent in failing to perform the duties and obligations  
17 imposed upon them under applicable federal and state statutes and common law.

18           840. Defendants also committed fraud by knowingly and intentionally  
19 making representations that were false. Defendants had a duty to disclose material  
20 facts and concealed them. These false representations and concealed facts were  
21 material to the conduct and actions at issue.

22           841. Defendants were selling and/or manufacturing dangerous drugs  
23 statutorily categorized as posing a high potential for abuse and severe dependence.  
24 Thus, Defendants knowingly traded in drugs that presented a high degree of  
25 danger if prescribed incorrectly or diverted to other than legitimate medical,  
26 scientific or industrial channels. Because of the severe level of danger posed by,  
27 and indeed visited upon the State and Plaintiffs' Community by, these dangerous  
28 drugs, Defendants owed a high duty of care to ensure that these drugs were only

1 used for proper medical purposes. Defendants chose profit over prudence and the  
2 safety of the community, and an award of punitive damages is appropriate as  
3 punishment and a deterrence. Punitive damages should be awarded pursuant to the  
4 common law and Cal. Civ. Code § 3294.

5 842. By engaging in the above-described wrongful conduct, Defendants  
6 also engaged in willful misconduct and gross negligence and exhibited an entire  
7 want of care that would raise the presumption of a conscious indifference to  
8 consequences.

9 **RELIEF**

10 **WHEREFORE**, Plaintiffs respectfully pray that this Court grant the following  
11 relief:

12 843. Entering Judgment in favor of The County in a final order against  
13 each of the Defendants;

14 844. Declare that Defendants have created a public nuisance in violation  
15 of California Civil Code Sections 3479 and 3480;

16 845. Enjoin the Defendants from performing any further acts in violation  
17 of California Civil Code Sections 3479 and 3480;

18 846. Order Defendants to fund an “abatement fund” on behalf of The  
19 People for the purposes of prospectively abating the ongoing opioid nuisance;

20 847. Order that Defendants compensate The County for damages to its  
21 property due to the ongoing public nuisance caused by the opioid epidemic;

22 848. Awarding actual damages, treble damages, injunctive and equitable  
23 relief, and forfeiture as deemed proper by the Court, and attorney fees and all  
24 costs and expenses of suit pursuant to The County’s racketeering claims;

25 849. Declare that Defendants have made, disseminated as part of a plan or  
26 scheme, or aided and abetted in the dissemination of false and misleading  
27 statements in violation of the California False Advertising Act;  
28

1           850. Enjoining the Defendants and their employees, officers, directors,  
2 agents, successors, assignees, merged or acquired predecessors, parent or  
3 controlling entities, subsidiaries, and all other persons acting in concert or  
4 participation with it, from engaging in false advertising in violation of the  
5 California False Advertising Act and ordering a temporary, preliminary or  
6 permanent injunction;

7           851. Order Defendants to pay restitution to The People of any money  
8 acquired by Defendants' false and misleading advertising, pursuant to the  
9 California False Advertising Act;

10          852. Order Defendants to pay civil penalties to The People of two  
11 thousand five hundred dollars (\$2,500) for each act of false and misleading  
12 advertising, pursuant to Section 17536 of the California False Advertising Act;

13          853. Awarding The County the damages caused by the opioid epidemic,  
14 and their negligent misrepresentations, fraud and deceit, including (A) costs for  
15 providing medical care, additional therapeutic and prescription drug purchases,  
16 and other treatments for patients suffering from opioid-related addiction or  
17 disease, including overdoses and deaths; (B) costs for providing treatment,  
18 counseling, and rehabilitation services; (C) costs for providing treatment of infants  
19 born with opioid-related medical conditions; (D) costs for providing care for  
20 children whose parents suffer from opioid-related disability or incapacitation; and  
21 (E) costs associated with law enforcement and public safety relating to the opioid  
22 epidemic;

23          854. Enter a judgment against the Defendants requiring Defendants to pay  
24 punitive damages to Plaintiffs;

25          855. Granting The County:

- 26           1. The cost of investigation, reasonable attorneys' fees, and all costs and  
27           expenses;
- 28           2. Pre-judgment and post-judgment interest; and,



1 3. All other relief as provided by law and/or as the Court deems  
2 appropriate and just.  
3

4 Dated: May 8, 2018

RESPECTFULLY SUBMITTED:

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6 CALIFORNIA, COUNTY OF  
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8 OFFICE OF THE COUNTY  
9 COUNSEL,  
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11 CALIFORNIA, Plaintiffs

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